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The information in this prospectus supplement is not complete and may be changed. This prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting offers to buy these securities, in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED July 14, 2011

PROSPECTUS SUPPLEMENT
(To Prospectus dated April 13, 2010)

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-165677

5,000,000 Shares

Common Stock

We are selling 5,000,000 shares of our common stock through this prospectus supplement and the accompanying prospectus.

Our common stock is listed on The NASDAQ Capital Market under the symbol "DCTH." The last reported sale price of our common stock on July 13, 2011 was $6.28 per share.

Investing in our common stock involves risks, including those described in the "Risk Factors" section beginning on page S-17 of this prospectus supplement and the section entitled "Risk Factors" beginning on page 10 of our most recent annual report on Form 10-K for the fiscal year ended December 31, 2010, which is incorporated by reference into this prospectus supplement and the accompanying prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriter has agreed to purchase the common stock from us at a price of $ per share which will result in $ of proceeds to us (before expenses). We have granted the underwriter a 30-day option to purchase up to an additional 750,000 shares of our common stock at a price of $ per share to cover any over-allotments which, if exercised in full, will result in an additional $ of proceeds to us (before expenses).

The underwriter may offer our common stock in transactions on The NASDAQ Capital Market, in the over-the-counter market or through negotiated transactions at market prices or negotiated prices.

Delivery of the shares of common stock is expected to be made on or about , 2011.

Sole Book-Running Manager

Jefferies

Prospectus Supplement dated July , 2011.

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About This Prospectus Supplement

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission using a shelf registration process. Under the shelf registration process, we may offer from time to time common stock, preferred stock, warrants, debt securities and stock purchase contracts. In the accompanying prospectus, we provide you with a general description of the securities we may offer from time to time under our shelf registration statement. In this prospectus supplement, we provide you with specific information about the shares of our common stock that we are selling in this offering. Both this prospectus supplement and the accompanying prospectus include important information about us, our common stock and other information you should know before investing. This prospectus supplement also adds, updates and changes information contained in the accompanying prospectus. You should read both this prospectus supplement and the accompanying prospectus as well as additional information described under “Where You Can Find Additional Information” on page S-2 of this prospectus supplement and on page 4 of the accompanying prospectus before investing in our common stock.

You should rely only on the information incorporated by reference or provided in this prospectus supplement and the accompanying prospectus or any free writing prospectus prepared by or on behalf of us. Neither we nor the underwriter have authorized anyone to provide you with additional or different information. If anyone provided you with additional or different information, you should not rely on it. Neither we nor the underwriter are making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed since those dates.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement contain certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this prospectus supplement, the accompanying prospectus and the other documents incorporated by reference that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus supplement, the accompanying prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 in Item 1A under "Risk Factors" as well as in Item 7A "Quantitative and Qualitative Disclosures About Market Risk," our Quarterly Report on Form 10-Q for the period ended March 31, 2011 in Part II, Item 1A under "Risk Factors" as well as in Part I, Item 3 "Quantitative and Qualitative Disclosures About Market Risk" and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- the progress and results of our research and development programs;
- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture and commercialize the Delcath chemosaturation system; and
- our ability to successfully negotiate and enter into agreements with strategic and corporate partners.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this prospectus supplement, the date of the accompanying prospectus or, in the case of documents incorporated by reference, as of the date of such documents. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus supplement or to reflect the occurrence of unanticipated events.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus, and any documents incorporated by reference. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus supplement is accurate as of any date other than the date on the front page of this prospectus supplement, regardless of the time of delivery of this prospectus supplement or any sale of securities.

We file reports, proxy statements and other information with the SEC. You may read and copy any reports, proxy statements or other information filed by us at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at (800) SEC-0330. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including Delcath Systems, Inc. The address of the SEC website is http://www.sec.gov.

Important Information Incorporated By Reference

The SEC allows us to "incorporate by reference" information into this prospectus supplement, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The documents incorporated by reference into this prospectus supplement contain important information that you should read about us.

The following documents are incorporated by reference into this document:

SEC Filing (File No. 001-16133)	Date of Filing
Quarterly Report on Form 10-Q for quarter ended March 31, 2011	May 5, 2011
Proxy Statement on Schedule 14A for our 2011 Meeting of Stockholders	April 27, 2011
Annual Report on Form 10-K for year ended December 31, 2010	March 8, 2011
Current Reports on Form 8-K and 8-K/A	January 25, 2011 February 23, 2011 April 1, 2011 April 14, 2011 May 4, 2011 June 10, 2011

We also incorporate by reference into this prospectus supplement all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial registration statement and prior to effectiveness of the registration statement, or (ii) from the date of this prospectus supplement but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

We will provide to each person, including any beneficial owner, to whom a prospectus supplement and the accompanying prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus supplement, other than exhibits which are specifically incorporated by reference into such documents. Requests should be directed to Controller at Delcath Systems, Inc., 810 Seventh Avenue, Suite 3505, New York, New York 10019 or by calling us at 212-489-2100.

SUMMARY

This summary highlights selected information more fully described elsewhere in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this prospectus supplement, the accompanying prospectus, any free writing prospectus and the documents incorporated by reference herein and therein carefully, especially the risks of investing in our common stock discussed in "Risk Factors" below and the other risks described in the incorporated documents.

In this prospectus supplement, except as otherwise indicated, "Delcath," "Delcath Systems," "we," "our," and "us" refer to Delcath Systems, Inc., a Delaware corporation and its subsidiary. "Delcath" is our registered United States trademark.

Company Overview

We are a development stage, specialty pharmaceutical and medical device company focused on oncology, initially cancers in the liver. Since our inception, we have directed our research efforts towards the development and clinical study of the Delcath chemosaturation system.

The Delcath chemosaturation system allows the administration of concentrated regional chemotherapy by isolating the circulatory system of the targeted organ. Once the organ is isolated, the Delcath chemosaturation system delivers high doses of chemotherapy agents, currently melphalan hydrochloride, or melphalan, directly to the liver, while limiting systemic exposure and the related side effects by filtering the blood prior to returning it to the patient. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs. We believe that the Delcath chemosaturation system is a platform technology that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body.

Prior to initiating our Phase III clinical trial, we submitted a proposal for the protocol's design, execution, and analysis under a Special Protocol Assessment, or SPA. A SPA is an evaluation by the U.S. Food and Drug Administration, or FDA, of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution, or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in a new drug application, or NDA, without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. We conducted our Phase III trial under a SPA.

In February 2010, we concluded a Phase III clinical trial for the Delcath chemosaturation system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver, which demonstrated a statistically significant improvement in hepatic progression-free survival, or hPFS, compared to the best alternative care. Our Phase III trial successfully met the study's primary endpoint of extended hPFS, demonstrating that the Delcath chemosaturation system with melphalan patients had a statistically significant longer median hPFS of 214 days compared to 70 days in the best alternative care control arm. This reflects a 144-day prolongation of hPFS over that of the best alternative care control arm, with less than half the risk of progression and/or death in the Delcath chemosaturation system with melphalan group compared to the best alternative care control group. In addition, we recently completed a multi-arm Phase II clinical trial of the Delcath chemosaturation system with melphalan in patients with primary and metastatic liver cancer.

Based on the Phase III results, we submitted our Section 505(b)(2) NDA, to the FDA in December 2010, seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. In February 2011, we received a Refusal to File RTF letter, or RTF, from the FDA for the NDA. The FDA will issue an RTF if it determines upon an initial review that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. At this time, the FDA has not requested additional studies to be conducted. We have had subsequent communications with the FDA, including a meeting in early April 2011 to discuss the issues raised and to confirm our understanding of the additional information required by the FDA in order to permit a substantive review of the application upon resubmission, which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA. Based on management's current understanding of the issues raised in the RTF and our subsequent communications with the FDA, we currently intend to resubmit an NDA by December 31, 2011.

On April 13, 2011, we obtained the right to affix the CE Mark to the Delcath chemosaturation system. The right to affix the CE mark allows us to market and sell the Delcath chemosaturation system in the European Economic Area, or EEA. In the EEA, the Delcath chemosaturation system is regulated as a medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote the Delcath chemosaturation system is limited to this approved indication. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath chemosaturation system and must use melphalan independently at their discretion.

We believe the Delcath chemosaturation system may ultimately fulfill an annual unmet clinical need for as many as 100,000 liver cancer patients in the EEA. We intend to focus our initial efforts on six target markets including Germany, United Kingdom, France, Netherlands, Italy and Spain. We believe these countries represent approximately 70% of the total potential liver cancer market in EEA countries. We intend to establish a European headquarters within the EEA and utilize third-party contract sales organizations, or CSOs, and a direct sales force in the United Kingdom, Germany and the Netherlands and distributors in France, Italy and Spain. We also intend to establish clinical training and centers of excellence to educate and train physicians and healthcare payors in these countries in order to develop key opinion thought leadership and foster initial market acceptance.

Advantages of the Delcath Chemosaturation System

Limited effective treatment options are currently available for liver cancer and they are generally associated with significant side effects and even death. Traditional treatment options include surgery, chemotherapy, radiation therapy, thermal therapy and chemoembolization as well as cryosurgery, percutaneous ethanol injection, implanted infusion pumps, surgically isolated perfusion and liver transplant. We believe the Delcath chemosaturation system may address the critical shortcomings of traditional liver cancer treatments based on the results of our Phase I, Phase II and Phase III trials:

- *Allows Higher Dosing* – Our Phase III clinical trial demonstrated that the Delcath chemosaturation system is capable of delivering up to ten times more of the chemotherapy agent to the treated region than traditional delivery methods. In our clinical studies on patients with metastatic melanoma it was shown that higher dosing led to significantly improved disease control in the liver.

- *Controls Toxicities* – Our Phase III clinical trial demonstrated that the Delcath chemosaturation system is capable of extracting on average 72% of the chemotherapy agent administered to the liver, which reduces the exposure of healthy tissue and organs to the effects of these chemotherapeutic agents.
- *Minimally Invasive and Repeatable* – The Delcath chemosaturation system allows for multiple courses of treatment with chemotherapeutic drugs and has a recovery period that is shorter than surgical resection.
- *Treats the Entire Liver* – By introducing the chemotherapeutic agent into the arterial blood supply feeding the liver, the Delcath chemosaturation system perfuses the entire liver with chemotherapy, treating both tumors that are visible as well as "micro metastases" that cannot be detected by imaging.

Strategy

We believe the Delcath chemosaturation system represents a potentially important new treatment option for cancers in the liver. We are seeking to establish the Delcath chemosaturation system as the standard regional therapy technique for the treatment of melanoma liver metastases and other liver cancer histologies.

We also intend to develop the system for use with other chemotherapeutic agents, as well as other drug compounds. We are continuing our research and development efforts with respect to other chemotherapeutic agents and the treatment of other types of cancer and will need to conduct additional clinical trials and seek approval for escalating doses of anti-cancer agents, including melphalan, for use with the Delcath chemosaturation system. As part of our development efforts, we intend to pursue U.S. pharmaceutical partners to co-develop and fund additional indications for the Delcath chemosaturation system.

Our strategy includes the following elements:

- *Commercialize the Delcath Chemosaturation System in the European Economic Area.* We intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly market the Delcath chemosaturation system in certain markets and enter into agreements with third-party distributors in others.
- *Leverage the CE Mark to Commercialize the Delcath Chemosaturation System in Other Countries*. We believe the right to affix the CE Mark can result in an accelerated regulatory approval in a number of countries outside the United States, including but not limited to Argentina, Australia, Brazil, China, Colombia, Dubai, Hong Kong, Japan, Jordan, Malaysia, Mexico, New Zealand, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, Thailand and Turkey. It is our intention to leverage the CE Mark in some or all of these countries to commercialize the Delcath chemosaturation system, where appropriate.
- *Obtain FDA Approval for Use of the Delcath Chemosaturation System in Combination with Melphalan to Treat Metastatic Melanoma in the Liver*. Based on management's current understanding of the issues raised in the RTF, we have begun to take action to address the FDA's concerns, and currently plan to resubmit our NDA to the FDA by December 31, 2011.
- *Commercialize the Delcath Chemosaturation System in the United States.* If we obtain FDA approval of our NDA, we intend to market the Delcath chemosaturation system with melphalan in the United States through our own sales force and focus our initial marketing efforts on major cancer centers beginning with those hospitals that participated in our Phase III clinical trial.

- *Establish Strategic Alliances.* We intend to pursue strategic partners to develop certain Asian markets including China, Korea and Japan. In the United States, we intend to pursue pharmaceutical partners to co-develop and fund other indications for the Delcath chemosaturation system.
- *Obtain Approval to Market the Delcath Chemosaturation System in the United States for the Treatment of Other Cancers in addition to Metastatic Melanoma in the Liver.* We recently concluded a multi-arm Phase II trial to evaluate the Delcath chemosaturation system for the treatment of other cancers in the liver, such as tumors of neuroendocrine and adenocarcinoma origin that have spread to the liver, primary liver cancer and melanomas in the liver that received certain prior regional treatment with melphalan. Upon successful conclusion of the related clinical trials, we intend to apply for regulatory approval of additional indications.
- *Expand the Application of the Delcath Chemosaturation System.* We intend to evaluate melphalan and other drug candidates for use with the Delcath chemosaturation system to treat other liver cancers, as well as other organs and body regions.

Sales and Marketing

Having obtained the right to affix the CE Mark in Europe, we plan to market and sell the Delcath chemosaturation system in the EEA. The EEA consists of the 27 member countries of the European Union as well as Lichtenstein, Iceland, and Norway. We intend to focus our initial efforts on six target markets including Germany, United Kingdom, France, Netherlands, Italy and Spain. We believe these countries represent approximately 70% of the total potential liver cancer market in EEA countries. We intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly and indirectly market the Delcath chemosaturation system. To pursue a direct marketing strategy in the United Kingdom, Germany and the Netherlands, we intend to utilize CSOs to make detailing calls to market our product to medical oncologists, and we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals. In France, Italy and Spain, where we intend to pursue an indirect marketing strategy, we will enter into agreements with third-party distributors.

Under the regulatory scheme in the EEA, the Delcath chemosaturation system has received authorization to affix the CE Mark as a device only. Melphalan is currently approved in 14 member states of the EEA, including the six countries we are initially targeting. Physicians must separately obtain melphalan for use with the Delcath chemosaturation system.

In the United States, if granted FDA approval, our intention is to market the system ourselves focusing our initial marketing efforts on the over fifty National Cancer Institute, or NCI, designated cancer centers in the United States, beginning with the hospitals which participated in the Phase III clinical trial. We plan to focus our efforts on three distinct groups of medical specialists:

- surgical oncologists who administer the Delcath chemosaturation system;
- medical oncologists who have initial responsibility for cancer patients; and
- interventional radiologists who are physicians specialized in working with catheter-based systems and who will also administer the Delcath chemosaturation.

We intend to utilize CSOs to make detailing calls to market our product to medical oncologists, and we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals.

Strategic Alliances

We plan to seek one or more corporate partners in other markets outside the United States, including Asia where we intend to pursue strategic partners to develop markets in China, Korea and Japan. Asia represents a potentially large market for the Delcath chemosaturation system, accounting for approximately 80% of the world's liver cancer patients. We also intend to leverage our CE Mark in order to expedite approval in select countries in Latin America and South America. We believe distribution or corporate partnering arrangements in select markets internationally will be cost effective, can be implemented more quickly than a direct sales force and will enable us to capitalize on local marketing expertise in the countries we target.

We believe that the Delcath chemosaturation system may have broader applicability, including using other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. As such, we also intend to pursue U.S. pharmaceutical partners to co-develop and fund possible additional indications for the Delcath chemosaturation system.

Risks of Investing

Investing in our securities involves risks. Potential investors are urged to read and consider the risk factors relating to an investment in the common stock set forth under "Risk Factors" in this prospectus supplement and the accompanying prospectus and those described in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC and incorporated by reference in this prospectus supplement and the accompanying prospectus as well as other information we include or incorporate by reference in this prospectus supplement and the accompanying prospectus.

Corporate Information

We were incorporated in the State of Delaware in August 1988. Our principal executive offices are located at 810 Seventh Avenue, Suite 3505, New York, New York 10019. Our telephone number is (212) 489-2100. Our website address is http://www.delcath.com. Information contained in our website is not a part of this prospectus supplement or the accompanying prospectus.

The Offering

Common stock offered by us	5,000,000 shares
Common stock to be outstanding after this offering	48,056,339 shares[1][2]
Use of proceeds	We intend to use the net proceeds from the sale of the shares for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital.
Dividend policy	We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes.
NASDAQ Capital Market symbol	DCTH
Risk Factors	See “Risk Factors” beginning on page S-17 of this prospectus supplement and other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus, including the section entitled “Risk Factors” beginning on page 10 of our most recent annual report on Form 10-K for the fiscal year ended December 31, 2010, for a discussion of the factors you should carefully consider before deciding to invest in our common stock.
Transfer Agent and Registrar	American Stock Transfer and Trust Company, LLC

Unless otherwise indicated, this prospectus supplement reflects and assumes no exercise by the underwriter of its overallotment option.

(1) The number of shares of common stock to be outstanding after this offering is based on 43,056,339 shares of common stock outstanding on July 13, 2011.

(2) The number of shares of common stock to be outstanding after this offering excludes, as of March 31, 2011:

- 4,140,629 shares issuable upon the exercise of stock options at a weighted average exercise price of $5.07 per share; and
- 2,512,934 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $3.51 per share.

Summary of Historical Financial Data

You should read the summary of historical financial data set forth below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operation" and the consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2010 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2011, each of which is incorporated by reference herein. We derived the following summary historical financial statement of operations data and other data for each of the three years in the period ended December 31, 2010 and the summary historical balance sheet data as of December 31, 2010 and 2009 from our audited financial statements. We derived the summary historical financial data as of and for the three months ended March 31, 2011 and 2010 from our unaudited financial statements. In our opinion, the unaudited financial statements have been prepared on the same basis as our audited financial statements and include all adjustments (consisting of only normal recurring adjustments) necessary for a fair presentation of the information set forth therein. The results for any interim period are not necessarily indicative of the results that may be expected for a full fiscal year.

Statement of operations data:	Three months ended March 31, 2011	Three months ended March 31, 2010	Year ended December 31, 2010	2009	2008
Cost and expenses:					
General and administrative expenses	$ 4,166,014	$ 2,546,172	$ 13,187,278	$ 3,898,705	$ 2,687,688
Research and development costs	3,648,224	2,941,110	17,555,698	9,637,050	5,378,335
Total costs and expenses	$ 7,814,238	$ 5,487,282	$ 30,742,976	$ 13,535,755	$ 8,066,023
Operating loss	(7,814,238)	(5,487,282)	(30,742,976)	(13,535,755)	(8,066,023)
Derivative instrument (expense) income	5,965,657	(8,687,717)	(15,951,367)	(8,567,917)	1,103,682
Interest income	559	1,264	10,698	73,833	299,956
Other (expense)/income	—	—	—	(26,753)	(202,500)
Interest expense	—	—	—	—	—
Net loss	$ (1,856,022)	$ (14,165,735)	$ (46,683,645)	$ (22,056,592)	$ (6,864,885)
Common share data:					
Basic and diluted loss per share	$ (0.04)	$ (0.39)	$ (1.20)	$ (0.82)	$ (0.27)
Weighted average number of basic and diluted common shares outstanding	42,953,553	36,261,688	38,991,481	27,072,556	25,300,703

Balance sheet data:	As of March 31, 2011	As of March 31, 2010	As of December 31, 2010	2009
Cash and cash equivalents	$ 39,284,758	$ 26,933,593	$ 45,621,453	$ 35,486,319
Total assets	43,283,653	32,234,339	50,577,709	36,807,041
Total liabilities	14,623,240	21,460,950	21,497,324	13,048,694
Accumulated deficit	(117,903,422)	(83,545,490)	(116,055,400)	(69,371,755)
Stockholders' equity	28,660,414	10,773,389	29,080,385	23,758,347

REGULATORY ENVIRONMENT

The Delcath chemosaturation system is subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

International Regulation

In order for our products to be marketed and sold in Asia, Europe, or other foreign jurisdictions, we must obtain the required regulatory approvals or clearances and comply with the extensive regulations regarding safety, manufacturing processes and quality requirements of the respective countries. These regulations, including the requirements for approvals to market, and the various regulatory frameworks may differ. In addition, there may be foreign regulatory barriers other than approval or clearance.

In the EEA, the Delcath chemosaturation system is subject to regulation as a medical device. The EEA is composed of the 27 Member States of the European Union and Norway, Iceland and Liechtenstein. Under the EU Medical Devices Directive (Directive No 93/42/ECC of 14 June 1993, as last amended), drug delivery products such as the Delcath chemosaturation system are governed by the EU laws on pharmaceutical products only if they are (i) placed on the market in such a way that the device and the pharmaceutical product form a single integral unit which is intended exclusively for use in the given combination, and (ii) the product is not reusable. In such cases, the drug delivery product is governed by the EU Code on Medicinal Products for Human Use (Directive 2001/83/EC, as last amended), while the essential requirements of the EU Medical Devices Directive apply to the safety and performance-related device features of the product. Because we do not intend to place the Delcath chemosaturation system on the EEA market as a single integral unit with melphalan, the product is governed solely by the EU Medical Devices Directive, while the separately marketed drug is governed by the EU Code relating to Medicinal Products for Human Use and other EU legislation applicable to drugs for human use.

Before we may commercialize a medical device in the EEA, we must comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification.

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices (i.e., Class I devices which are non-sterile and do not have a measuring function), the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EEA to conduct conformity assessments. For Class III medical devices, such as the Delcath chemosaturation system, before issuing a certification indicating compliance with the essential requirements, a Notified Body will typically audit a manufacturer's quality system for the design, manufacture, and final inspection of the medical devices, and examine the specific design dossier of the products covered by the conformity assessment. Based on this certification, manufacturers can complete an EC Declaration of Conformity which allows them to affix the CE mark to their products.

A manufacturer without a registered place of business in a Member State of the European Union which places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer's behalf with regard to the manufacturer's obligations under the EU Medical Devices Directive. We have appointed such a representative, although we are in the process of establishing our infrastructure in the EEA and expect that we will not need a third party representative in the future.

On April 13, 2011, we obtained the required certification from Lloyd's Register Quality Assurance, or LRQA, a UK notified body, for the Delcath chemosaturation system with the following labeled indication: intra-arterial administration of the chemotherapeutic agent melphalan hydrochloride to the liver with additional extracorporeal flirtation of the venous blood return. Based on this certification, we can complete an EC Declaration of Conformity and affix the CE mark to the Delcath chemosaturation system.

Although the Delcath chemosaturation system is CE marked, the provisions of the EU Medical Devices Directive are implemented into the national laws of the Member States of the European Union, which may impose additional conditions on the commercialization of medical devices within their territory, including, for example, language used on the device's labeling. These Member State national laws are enforced by the respective competent authorities of each Member State, which may differ on the interpretation of the provisions of the EU Medical Device Directive as implemented into their national laws. Therefore, complying with the regulations of one Member State does not automatically ensure compliance in other Member States.

In the EEA, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of incidents related to the use of a medical device. Under this system, incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a contributory cause of an incident, its manufacturer or authorized representative in the European Union must report it to the Competent Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer's investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action, or FSCA. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include, device recall, modification exchange and destruction. FSCAs must be notified by the manufacturer or its authorized representative to its customers and/or the end users of the medical device via a Field Safety Notice.

In the EEA, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath chemosaturation system and must use melphalan independently at their discretion.

In the EEA, the advertising and promotion of our products is also subject to EEA Member States laws implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Failure to comply with the EEA Member State laws implementing the Medical Devices Directive, with the EU and EEA Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the EEA Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

The European Commission is currently reviewing the medical devices legislative framework with the aim of simplifying it and ensuring a more uniform application of the provisions contained in the medical devices directives across the EEA. These adopted or expected regulatory changes may adversely affect our business, financial condition and results of operations or restrict our operations.

United States Regulation

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations. The Delcath chemosaturation system is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Delcath chemosaturation system, the primary mode of action is attributable to the drug component of the product, which means that the center for Drug Evaluation and Research, or CDER, has primary jurisdiction over its pre-market development and review. The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health

risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the U.S. IND are required in the EEA and other jurisdictions in which we may conduct clinical trials.

Clinical Trials. For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- *Phase I Clinical Trials*. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.
- *Phase II Clinical Trials.* Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials.
- *Phase III Clinical Trials.* These are commonly referred to as pivotal studies. When Phase II evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.
- *Phase IV Clinical Trials.* The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase IV clinical trials.

Sponsors of clinical trials may submit proposals for the design, execution, and analysis for their pivotal trials under a SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. Prior to initiating our Phase III clinical trial, we submitted a proposal for the design, execution and analysis under a SPA, and we conducted our Phase III trial under a SPA.

New Drug Applications. The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which is may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. The FDA may deny approval of an NDA by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

In December 2010, we submitted our NDA for the Delcath chemosaturation system under Section 505(b)(2) of the FFDCA seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA's findings of safety and effectiveness for previously approved products, such as melphalan. Melphalan, the drug we are initially seeking to have approved for use with the Delcath chemosaturation system, is a widely used chemotherapy agent that has already been approved by the FDA for use at a lower dose than we used in our Phase III clinical trial. The approved labeling for melphalan includes indications for use, method of action, dosing, side effects and contraindications. Because the Delcath chemosaturation system delivers the drug through a different mode of administration and at a dose strength that is substantially higher than that which is currently approved, we will be seeking a revised label of melphalan for use with the Delcath chemosaturation system through its Section 505(b)(2) NDA. The clinical trials were designed to provide the necessary clinical data to support this required labeling change.

In accordance with applicable regulations, the FDA has the ability to formally file or refuse to file an application within 60 days of the completion of the submission. The FDA will issue a Refusal to File letter, or RTF, if it determines upon an initial review that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. In February 2011, we received an RTF from the FDA for the NDA. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. We have had subsequent communications with the FDA, including a meeting in early April to discuss the issues raised and to confirm our understanding of the additional information required by the FDA in order to permit a substantive review of the application upon resubmission, which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA. Based on management's current understanding of the issues raised in the RTF and our subsequent communications with the FDA, we currently intend to resubmit an NDA by December 31, 2011 which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA.

Upon resubmission of our application, the FDA will again perform an initial review to assess whether the NDA is sufficiently complete to warrant a substantive review. If the FDA agrees to formally file the application, it will issue a Prescription Drug User Fee Act, or PDUFA, action date. If the drug is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrates the potential to address unmet medical needs for the condition, the sponsor may be subject to a Fast Track designation. The Fast Track program is a process designed to facilitate the development and expedite the review of drugs to treat serious diseases and fill an unmet medical need. Under the program, the sponsor of a new drug may request that the FDA designate the drug for a specific indication as a fast track product concurrent with or after the IND is filed for the product candidate, and the FDA must determine if the product qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. The Delcath chemosaturation system has received a Fast Track designation. A drug that receives Fast Track designation may be eligible for more frequent meetings with FDA to discuss the drug's development; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials; eligibility for accelerated approval, i.e., approval of an effect on a surrogate, or substitute endpoint; and rolling review, meaning the sponsor may submit its NDA in sections rather than wait until the entire NDA is complete, among others. Most drugs with Fast Track designation are likely to be considered appropriate to receive a Priority Review. In 1992, under PDUFA, the FDA created a two-tiered system of review times – Standard Review and Priority Review. Standard Review is applied to a drug that offers at most, only minor improvement over existing marketed therapies with a goal of completing the FDA review of the NDA within a ten-month time frame. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes FDA to review a new drug application is reduced. The goal for completing a Priority Review is six months. We intend to request a Priority Review in our resubmitted NDA to the FDA. We cannot guarantee that our application for approval of the Delcath chemosaturation system will receive a Priority Review, or that if Priority Review is received, that the review or approval will be faster than conventional FDA procedures or that FDA will ultimately grant approval.

Orphan Drug Exclusivity. Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting. The FDA has granted us four orphan drug designations. In November 2008, the FDA granted us two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted us an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted us an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. If the Delcath chemosaturation system is approved for an indication different than the indications for which we have received orphan drug designations, we will not obtain orphan drug exclusivity.

Other Regulatory Requirements. Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. The Delcath chemosaturation system, if approved by the FDA, may be subject to REMS requirements that affect labeling, distribution or post market reporting. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw approval of the NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for

many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use. Thus, we may only market the Delcath chemosaturation system, if approved by the FDA, for its approved indications and we could be subject to enforcement action for off-label marketing.

RISK FACTORS

Any investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and all of the information contained in this prospectus supplement and the accompanying prospectus before deciding whether to purchase our common stock. In addition, you should carefully consider, among other things, the matters discussed under "Risk Factors" and "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2010 and in our Quarterly Report on Form 10-Q for the period ended March 31, 2011, and in other documents that we subsequently file with the Securities and Exchange Commission, all of which are incorporated by reference. The risks and uncertainties described below and incorporated by reference are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of these risks actually occur, our business, financial condition and results of operations would suffer. In that event, the trading price of our common stock could decline, and you may lose all or part of your investment. This prospectus supplement, the accompanying prospectus and the incorporated documents also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements. See "Disclosure Regarding Forward-Looking Statements."

Risks Related to Our Business and Financial Condition

If we are unable to develop the Delcath chemosaturation system, obtain regulatory approval outside the EEA or market and sell the system, we will not generate operating revenue or become profitable.

The Delcath chemosaturation system, a platform technology for the isolation of various organs or regions of the body to permit the regional delivery of high doses of drugs, is our only product. Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of this product and currently we have only developed this system for the treatment of cancers in the liver with melphalan. If the Delcath chemosaturation system with melphalan fails as a commercial product, we have no other products to sell. In addition, since the Delcath chemosaturation system is currently only authorized for marketing in the EEA, if we are unsuccessful in commercializing the product in the EEA and the Delcath chemosaturation system is not approved in the United States and elsewhere, we will have no other means of generating revenue.

Continuing losses may exhaust our capital resources.

As of March 31, 2011, we had $39.3 million in cash, cash equivalents and certificates of deposit. We have had no revenue to date, a substantial accumulated deficit, recurring operating losses and negative cash flow. We expect to continue to incur losses while generating minimal revenues over the next year. From our inception on August 5, 1988 through March 31, 2011, we have incurred cumulative net losses of approximately $116.5 million. For the three months ended March 31, 2011 and years ended December 31, 2010, 2009 and 2008, we incurred net losses of approximately $1.9 million, $46.7 million, $22.1 million and $6.9 million, respectively, with these amounts being effected by derivative accounting related to warrants as described in our Annual Reports on Form 10-K for the years ended December 31, 2010, 2009 and 2008. To date, we have funded our operations through a combination of private placements and public offerings of our securities. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, product development, regulatory approval process and commercialization of the Delcath chemosaturation system with melphalan or any other versions of the system.

If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to commercialize the Delcath chemosaturation system, resubmit our NDA to the FDA or conduct future development and clinical trials.

We may require additional financing to commercialize our product in the EEA and any other markets where we receive approval for our system, to resubmit our NDA seeking U.S. marketing approval or seek other approvals and to conduct future development and clinical trials. We do not know if additional financing will be available when needed at all or on acceptable terms. If we are unable to obtain additional financing as needed, we may not be able to sell the Delcath chemosaturation system commercially, obtain regulatory approvals or complete our trials.

Our liquidity and capital requirements will depend on numerous factors, including:

- our research and product development programs, including clinical studies;
- the timing and costs of our various U.S. and foreign regulatory filings, obtaining approvals and complying with regulations;
- the timing and costs associated with developing our manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements overseas;
- the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

Insufficient funds may require us to curtail or stop our commercialization activities, submissions for regulatory approval, research and development and clinical trials, which will significantly limit our potential to generate future revenues.

Risks Related to FDA and Foreign Regulatory Approval

Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations.

The Delcath chemosaturation system is subject to extensive and rigorous government regulation by the FDA and other foreign regulatory agencies. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical and medical device products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions.

In the United States, the FDA regulates drug and device products under the FFDCA, and its implementing regulations. The Delcath chemosaturation system is subject to regulation by the FDA as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of the product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Delcath chemosaturation system, the primary mode of action is attributable to the drug component of the product, which means that the CDER has primary jurisdiction over its pre-market development and review.

We are not permitted to market the Delcath chemosaturation system in the United States unless and until we obtain regulatory approval from the FDA. To market the product in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. Regulatory approval of an NDA is not guaranteed. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;

- may not find the data from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we do;
- may not approve the manufacturing processes or facilities associated with our product candidates;
- may change approval policies (including with respect to our product candidates' class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Undesirable side effects caused by any product candidate that we develop could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us to evaluate the future of our development programs. The regulatory review and approval process is lengthy, expensive and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is ten months for a standard application and six months for a priority review application. The FDA's review goals are subject to change and it is unknown whether the review of an NDA filing for any of our product candidates will be completed within the FDA's review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other NDAs that are submitted to FDA around the same time period. The development and approval process may take many years, require substantial resources and may never lead to the approval of a product. Failure to obtain or delays in obtaining, regulatory approvals may:

- adversely affect the commercialization of the current Delcath chemosaturation system or any products that we develop in the future;
- impose additional costs on us;
- diminish any competitive advantages that may be attained; and
- adversely affect our ability to generate revenues.

We have obtained the right to affix the CE Mark for the Delcath chemosaturation system as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with the Delcath chemosaturation system, our ability to commercialize the Delcath chemosaturation system in the EEA will be significantly limited.

In the EEA, the Delcath chemosaturation system is regulated as a medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote the Delcath chemosaturation system is limited to this approved indication. To the extent that our promotion of the Delcath chemosaturation system is found to be outside the scope of our approved indication, we may be subject to fines or other regulatory action, limiting our ability to commercialize the Delcath chemosaturation system in the EEA.

Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. As a result, the delivery of melphalan with our device may not be within the applicable melphalan label with respect to some indications in some Member States of the EEA where the drug is authorized for marketing. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not

approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath chemosaturation system and must use melphalan independently at their discretion. If physicians are unwilling to obtain melphalan separately from our product and/or to prescribe the use of melphalan independently, our sales opportunities in the EEA will be significantly impaired.

While we have obtained the right to affix the CE Mark, we will be subject to significant ongoing regulatory obligations and oversight in the EEA and in any other country where we receive marketing authorization or approval.

In April 2011, we obtained the required certification from our European Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Devices Directive and affix the CE Mark to the Delcath chemosaturation system. In order to maintain the right to affix the CE Mark in the EEA, we are subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we will be subject to ongoing audits by our European Notified Body, and the right to affix the CE Mark to the Delcath chemosaturation system may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that the Delcath chemosaturation system is approved by the FDA or any other regulatory agency, we will be subject to similar ongoing regulatory obligations and oversight in those countries where we obtain approval. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices, or GCPs, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any clinical trials that we conduct post-approval. In addition, post-marketing requirements for the Delcath chemosaturation system may include implementation of a REMS to ensure that the benefits of the product outweigh its risks. A REMS may include a Medication Guide, a patient package insert, a communication plan to healthcare professionals and/or other elements to assure safe use of the product.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, Warning Letters or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

The development and approval process in the United States may take many years, require substantial resources and may never lead to the approval of the Delcath chemosaturation system by the FDA for use in the United States.

We cannot sell or market the Delcath chemosaturation system with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for the Delcath chemosaturation system. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or other chemotherapeutic agent used in our system. We are seeking approval of the Delcath chemosaturation system for a substantially higher dose of melphalan than prior approved doses of melphalan and such other drugs. We must obtain separate regulatory approvals for the Delcath chemosaturation system with melphalan and every other chemotherapeutic agent or other compound used with our system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA's satisfaction the product's safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of the Delcath chemosaturation system with melphalan or any other chemotherapeutic agent or compound we use in our system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete our clinical trials. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for our system and our use of melphalan or other chemotherapeutic agents, the value of our company and our results of operations will be harmed.

In December 2010, we submitted our Section 505(b)(2) NDA to the FDA, seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. An NDA submitted under Section 505(b)(2) of the FFDCA permits the application to incorporate information required for approval from studies not conducted by or for the application and for which the applicant has not obtained a right of reference. Our Section 505(b)(2) application cited the safety information for melphalan submitted by prior NDA applicants for this drug. In February 2011, we received an RTF from the FDA for the NDA. In accordance with applicable regulations, the FDA has the ability to formally file or refuse to file an application within 60 days of the completion of the submission. The FDA will issue an RTF if it determines upon an initial review that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. We have had subsequent communications with the FDA, including a meeting in early April to discuss the issues raised and to confirm our understanding of the additional information required by the FDA in order to permit a substantive review of the application upon resubmission. Based on management's current understanding of the issues raised in the RTF and our subsequent communications with the FDA, we currently intend to resubmit an NDA by December 31, 2011 which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA. If we are unable to properly address the issues raised in the RTF to the FDA's satisfaction, we may be unable to resubmit our NDA to the FDA. Further, if we resubmit the NDA and subsequently receive a second RTF from the FDA, or, if it is accepted for filing and the FDA fails to approve the application after a substantive review, we will not be able to commercialize the Delcath chemosaturation system in the United States and our value and our results of operations will be harmed.

Even if we obtain regulatory approval for the Delcath chemosaturation system in the United States, our ability to market the Delcath chemosaturation system would be limited to those uses that are approved.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. In the United States, we intend to seek approval for use of the Delcath chemosaturation system with melphalan in the treatment of ocular and cutaneous melanoma that has metastasized to the liver. If the FDA approves this application, our ability to market and promote the Delcath chemosaturation system would be limited to this indication for use only with melphalan in treating that specific disease, so even with FDA approval, the Delcath chemosaturation system may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, including oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product. Thus, we may only market the Delcath chemosaturation system, if approved by the FDA, for its approved indication and we could be subject to enforcement action for off-label marketing.

Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

If we do not obtain required approvals in the United States and in the countries outside of the EEA in which we aim to market the Delcath chemosaturation system, we may not be able to export or sell the Delcath chemosaturation system in those markets, which will limit our sales opportunities.

We intend to leverage our CE Mark to obtain required regulatory approvals for the Delcath chemosaturation system in other parts of the world, including Asia. However, our lack of experience conducting clinical trials outside the United States may negatively impact the approval process in foreign countries where we intend to seek approval for the Delcath chemosaturation system. We have not previously conducted multi-national clinical trials, and, particularly in countries where melphalan has not yet been approved, obtaining approval for the Delcath chemosaturation system may be challenging.

If we are unable to obtain and maintain required approval from one or more foreign countries outside of the EEA where we would like to sell the Delcath chemosaturation system, we will be unable to market our product as intended, our international market opportunity will be limited and the value of our company and our results of operations will be harmed.

If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market the Delcath chemosaturation system for other indications.

The clinical trial data on our product is limited to specific types of liver cancer. In 2010, we concluded a Phase III clinical trial of the Delcath chemosaturation system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver and recently completed a multi-arm Phase II clinical trial of the Delcath chemosaturation system with melphalan in patients with primary and metastatic melanoma stratified into four arms. We currently have no clinical trials on any other major forms of liver cancer.

We intend to conduct clinical trials for other indications, and it may take several years to complete the testing of the Delcath chemosaturation system with melphalan, other chemotherapeutic agents or other compounds for use in the treatment of the indications we wish to obtain approval of, and failure can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;

- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system or the period required for review of any application for regulatory agency approval;
- our clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA may request additional clinical trials, including an additional Phase III trial, relating to our NDA submissions;
- the FDA may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

The failure or delay of clinical trials could cause an increase in the cost of product development, delay filing of an application for marketing approval or cause us to cease the development of the Delcath chemosaturation system for other indications. If we are unable to develop the Delcath chemosaturation system for other indications the future growth of our business could be negatively impacted.

While we have received approval of our clinical trial protocol from the FDA under a SPA, our failure to execute the clinical trial according to the agreed upon trial protocol may result in loss of FDA approval and invalidation of our clinical trials.

Prior to initiating our Phase III clinical trial, we submitted a proposal for the design, execution, and analysis under a SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution, or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor’s agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. Pursuant to the FDA’s guidance on SPAs, a SPA is documented in a SPA letter and/or the minutes of a Type A meeting. We conducted our Phase III trial under a SPA. The SPA may be invalidated for a number of reasons including our failure to execute the clinical trial according to the agreed upon trial protocol. While we believe our SPA is currently valid, our failure to execute the clinical trial according to the agreed upon trial procedures, or the FDA’s identification of a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins, may lead to the invalidation of the SPA, and as a result, the trial itself may not be sufficient to serve as the primary basis of an effectiveness claim.

We rely on third parties to conduct certain of the clinical trials for the Delcath chemosaturation system, and if they do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system.

We design the clinical trials for the Delcath chemosaturation system, but we rely on academic institutions, corporate partners, contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials. We rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. In particular, we relied on a third party to conduct monitoring of our Phase II and Phase III clinical trials and collect the data for our planned resubmission of an NDA. We intend to rely upon third parties to conduct monitoring and data collection of our future clinical trials. Although we rely on these third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties does not relieve us of these responsibilities and requirements, and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA's cGMP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and we may fail to obtain regulatory approval for the Delcath chemosaturation system if these requirements are not met.

Purchasers of the Delcath chemosaturation system in the EEA may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, we may not be able to successfully commercialize the Delcath chemosaturation system in the EEA.

We have obtained the right to affix the CE Mark for the Delcath chemosaturation system, and we intend to seek third-party or government reimbursement within those countries in the EEA where we expect to market and sell the Delcath chemosaturation system. Until we obtain government reimbursement, we will rely on private payors or local pre-approved funds where available. New technology payment programs may provide interim funding, but there are no assurances that we will qualify for such funding. Even if we do qualify, the amount and the duration of this funding may be limited. There are also no assurances that third-party payors or government health agencies of members states of the EEA will reimburse the product's use in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in other EEA countries. Physicians, hospitals and other health care providers may be reluctant to purchase the Delcath chemosaturation system if they do not receive substantial reimbursement for the cost of using our product from third-party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in the EEA.

As the Delcath chemosaturation system is not currently approved by the FDA or other regulatory bodies outside the EEA, third-party payors in the United States and elsewhere will not reimburse the use of our product. Even if approval is obtained, inadequate reimbursement may harm results of operations.

The Delcath chemosaturation system is currently not approved by the FDA or any other regulatory body outside the EEA. Medicare, Medicaid, private health insurance plans and their foreign equivalents will not reimburse the Delcath chemosaturation system's use since the product is currently not approved outside the EEA. We will seek reimbursement by third-party payors of the cost of the Delcath chemosaturation system after its use is approved, but there are no assurances that third-party payors in the United States or other countries will agree to cover the cost of procedures using the Delcath chemosaturation system at all or at rates that are adequate to cover the actual costs. Further, third-party payors may deny reimbursement if they determine that the Delcath chemosaturation system is not used in accordance with established payor protocols regarding cost effective treatment methods or is used outside its approved indication or for forms of cancer or with drugs not specifically approved by the FDA or other foreign regulatory bodies in the future. Without reimbursement, physicians, hospitals and other health care providers will be less likely to purchase the Delcath chemosaturation system, thereby harming our results of operations.

Risks Related to Manufacturing, Commercialization and Market Acceptance of the Delcath Chemosaturation System

There is only one approved third-party manufacturer of melphalan in the EEA. If this manufacturer fails to provide end-users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities, we may be unable to successfully commercialize our product in the EEA.

Under the regulatory scheme in the EEA, the Delcath chemosaturation system is approved for marketing as a device only, and doctors will separately obtain melphalan for use with the Delcath chemosaturation system. Although melphalan has been approved in the EEA for over a decade, we are aware that there is currently only one approved manufacturer of melphalan in the EEA, with whom we have no supply arrangements or other affiliation, and therefore we will not have any control over the quality, availability, price or labeling of melphalan in that market. As a result, there may not be sufficient supply of melphalan for use with our system, and any adverse change in the sole manufacturer's commercial operations or regulatory approval status may seriously impair our sales opportunities in the EEA. Additionally, melphalan is not available in certain foreign countries outside the EEA where we intend to market the Delcath chemosaturation system. If supply of melphalan remains limited or unavailable, we will be unable to commercialize our product in these markets, thereby limiting future sales opportunities.

We purchase components for the Delcath chemosaturation system from third parties, some of which are sole-source suppliers.

The components of the Delcath system, including catheters, filters, introducers and chemotherapy agents, must be manufactured and assembled in accordance with approved manufacturing and predetermined performance specifications and must meet cGMP and quality systems requirements. Some states also have similar regulations. Many of the components of the Delcath chemosaturation system are manufactured by sole-source suppliers that may have proprietary manufacturing processes. If Delcath or any of our suppliers fails to meet those regulatory obligations, we may be forced to suspend or terminate our clinical trials, and, once a product is approved for marketing, the manufacture, assembly or distribution thereof. Further, if we need to find a new source of supply, we may face long interruptions in obtaining necessary components for the Delcath chemosaturation system, in obtaining FDA or foreign regulatory agency approval of these components and in establishing the manufacturing process, which could jeopardize our ability to supply the Delcath chemosaturation system to the market.

All of the manufacturers of the components for the Delcath chemosaturation system must comply with a number of FDA and International Organization for Standardization, or ISO, and foreign regulatory agency requirements and regulations. If we or one of our suppliers fails to meet such requirements, we may need to change suppliers. If we are unable to successfully change suppliers, the successful completion of some of our future clinical trials and/or commercialization of the Delcath chemosaturation system could be jeopardized.

If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents we will be unable to successfully commercialize the Delcath system in the United States.

We have entered into a manufacturing and supply agreement with Synerx Pharma, LLC, or Synerx, and Bioniche Teoranta, or Bioniche, an affiliate of Mylan, Inc., for the supply of our branded melphalan for injection. The agreement with Synerx and Bioniche currently represents our sole source of branded melphalan in the United States. We intend to pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents that we will use in the future for the commercialization of the Delcath chemosaturation system, as well as for labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. To manufacture melphalan or other chemotherapeutic agents on our own, we would first

have to develop a manufacturing facility that complies with FDA requirements and regulations for the production of melphalan and each other chemotherapeutic agent we choose to manufacture for our system. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability. If we are unable to obtain sufficient melphalan and labeling services on acceptable terms, if we should encounter delays or difficulties in our relationships with our current and future suppliers or if our current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan, our business, financial condition and results of operations may be materially harmed.

If we cannot successfully manufacture the Delcath chemosaturation system, our ability to develop and commercialize the system would be impaired.

We will manufacture the Delcath chemosaturation system for distribution in the EEA in our Queensbury, NY facility. We have a limited manufacturing history and we may not be able to manufacture the system in commercial quantities, in a cost-effective manner or in compliance with the regulatory requirements applicable to such manufacturing. Additionally, we may have difficulty obtaining components for the system from our third-party suppliers in a timely manner or at all which may adversely affect our ability to deliver the Delcath chemosaturation system to purchasers.

In addition to limiting sales opportunities, delays in manufacturing the Delcath chemosaturation system may adversely affect our ability to obtain regulatory approval in other jurisdictions. Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the system, including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements. If we are unable to manufacture the Delcath chemosaturation system in a timely manner, we may not be able to conduct the clinical trials required to obtain regulatory approval and commercialize our product.

If our Queensbury, NY facility fails to maintain compliance with ISO 13485, a comprehensive management system for the design and manufacture of medical devices, and FDA cGMP or fails to pass facility inspection or audits, our ability to manufacture at the facility could be limited or terminated. In the future, we may manufacture and assemble the Delcath chemosaturation system in the EEA, and any facilities in the EEA would have to obtain and maintain similar approvals or certifications of compliance.

We do not have written contracts with all of our suppliers for the manufacture of components for the Delcath chemosaturation system.

We do not have written contracts with all our suppliers for the manufacture of components for the Delcath chemosaturation system. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we may not be able to manufacture the system in commercial quantities or in a cost-effective manner, and commercialization of the Delcath chemosaturation system in the EEA may be delayed. In addition, certain components are available from only a limited number of sources. Components of the Delcath chemosaturation system are currently manufactured for us in small quantities for use in our preclinical and clinical studies. We will require significantly greater quantities to commercialize the product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from our existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of the Delcath chemosaturation system may be delayed.

We have limited experience in marketing and commercializing our products, and as a result, we may not be successful in commercializing the Delcath chemosaturation system in the EEA.

We intend to pursue a two-pronged commercialization strategy in the EEA under which we will directly and indirectly market the Delcath chemosaturation system. To pursue a direct marketing strategy in the United Kingdom, Germany and the Netherlands, we intend to utilize CSOs to make detailing calls to market our product to medical oncologists, and we intend to utilize a direct sales force to sell our product to interventional radiologists and hospitals. In France, Italy and Spain, where we intend to pursue an indirect marketing strategy, we will enter into agreements with third-party distributors. However, we have not previously sold, marketed or distributed any

products and have limited experience in building a sales and marketing organization and in entering into and managing relationships with third-party distributors. Even though we have obtained the right to affix the CE Mark, we currently have no sales, marketing, commercial or distribution capabilities in any countries in the EEA. In order to pursue our strategy to commercialize the Delcath chemosaturation system in the EEA, we must acquire or internally develop a sales, marketing and distribution infrastructure and/or enter into strategic alliances to perform these services. The development of sales, marketing and distribution infrastructure is difficult, time consuming and requires substantial financial and other resources. If we cannot successfully develop the infrastructure to market and commercialize the Delcath chemosaturation system, our ability to generate revenues in the EEA may be harmed, and we may be required to enter into strategic alliances to have such activities carried out on our behalf, which may not be on favorable terms.

Competition for sales and marketing personnel is intense, and we may not be successful in attracting or retaining such personnel. Our inability to attract and retain skilled sales and marketing personnel or to reach an agreement with a third party could adversely affect our business, financial condition and results of operations. Further, since our marketing strategy in the EEA includes establishing a network of third-party distributors, we must enter into collaborative arrangements with these third-party distributors. We may not be able to enter into such arrangements on reasonable terms or at all.

Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing the Delcath chemosaturation system in markets outside the EEA, because of inadequate infrastructure or an ineffective commercialization strategy.

Outside the EEA, even if we obtain regulatory approval from the FDA or other foreign regulatory agencies, our ability to commercialize the Delcath chemosaturation system may be limited due to our inexperience in developing a sales, marketing and distribution infrastructure. In the United States, we intend to develop and train our own sales force to market our products, and in foreign countries other than in the EEA, we intend to market our products primarily through strategic partners and distributors. If we are unable to develop this infrastructure in the United States or to collaborate with an alliance partner to market our products in foreign countries, particularly in Asia, our efforts to commercialize the Delcath chemosaturation system or any other product outside of the EEA may be less successful.

Even if we are successful in commercializing the Delcath chemosaturation system in the EEA, we may not be successful in the United States and other foreign countries. Each country requires a different commercialization strategy, so our EEA strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, our efforts to promote and market the Delcath chemosaturation system in each of our target markets may fail in any or all of those markets.

Our plan to use collaborative arrangements with third parties to help finance and to market and sell the Delcath chemosaturation system may not be successful.

We have entered into a collaborative agreement with Chi Fu Trading Company for the country of Taiwan and intend to enter into one or more strategic alliances to further address markets outside the United States, particularly in Asia, and to help fund the development of additional indications or for use with additional chemotherapy agents within the United States. We may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials. Additionally, we may face competition in our search for alliances. As a result, we may not be able to enter into any additional alliances on acceptable terms, if at all.

Our collaborative relationships may never result in the successful development or commercialization of the Delcath chemosaturation system or any other product. The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may

have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We are not able to control or influence the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with the Delcath chemosaturation system or the withdrawal of their support for our products. The failure of any such collaboration could have a material adverse effect on our business.

If we fail to overcome the challenges inherent in international operations, our business and results of operations may be materially adversely affected.

Currently we have only received authorization to market the Delcath chemosaturation system in the EEA and intend to seek similar authorization or approvals in other foreign countries. As a result, we expect international sales of our products to account for a significant portion of our revenue, which exposes us to risks inherent in international operations. To accommodate our international sales, we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers. Accordingly, we will face additional risks resulting from our international operations including:

- difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;
- the failure to fulfill foreign regulatory requirements to market our products on a timely basis or at all;
- availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign sales or marketing employees and agents;
- limited protection for intellectual property rights in some countries;
- fluctuations in currency exchange rates;
- the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the possibility of any material shipping delays;
- significant changes in the political, regulatory, safety or economic conditions in a country or region;
- protectionist laws and business practices that favor local competitors; and
- trade restrictions, including the imposition of, or significant changes to, the level of tariffs, customs duties and export quotas.

If we fail to overcome the challenges we encounter in our international operations, our business and results of operations may be materially adversely affected.

The Delcath chemosaturation system has never been used in a clinical setting in the EEA, so market acceptance of our product will depend on EEA healthcare professionals' efforts to learn about our product.

Since all of our prior clinical studies were conducted in the United States and the Delcath chemosaturation system has never been used in a clinical setting in the EEA, physicians in the EEA have no clinical experience with our product. As a result, the Delcath chemosaturation system may not gain significant market acceptance among physicians, hospitals, patients and healthcare payors in the EEA until healthcare professionals are properly educated about the procedure. Market acceptance of the Delcath chemosaturation system in the EEA will depend upon a variety of factors including:

- whether our future clinical trials demonstrate significantly improved patient outcomes;

- our ability to educate and train physicians to perform the procedure and drive acceptance of the use of the Delcath chemosaturation system;
- our ability to convince healthcare payors that use of the Delcath chemosaturation system results in reduced treatment costs and improved outcomes for patients;
- whether the Delcath chemosaturation system replaces and/or complements treatment methods in which many hospitals have made a significant investment; and
- whether doctors and hospitals are willing to replace their existing technology with a new medical technology until the new technology's value has been demonstrated.

We intend to establish clinical training and centers of excellence to educate and train physicians and healthcare payors in the EEA, but the key opinion thought leadership required for initial market acceptance within the healthcare arena may take time to develop. Without effort from healthcare professionals to become educated about our product, the market may not accept the Delcath chemosaturation system and our efforts to commercialize the Delcath chemosaturation system in the EEA may be unsuccessful.

Similar considerations apply in any other market where we receive approval. Successful commercialization of the Delcath chemosaturation system in these markets will depend on market acceptance by healthcare professionals.

Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could affect our ability to achieve meaningful revenues or profit.

Competition in the cancer treatment industry is intense. The Delcath chemosaturation system competes with all forms of liver cancer treatments that are alternatives to the "gold standard" treatment of surgical resection. Many of our competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective or more affordable products or treatment methods, or achieve earlier product development, our revenues or profitability will be substantially reduced.

The loss of key personnel could adversely affect our business.

The loss of a member of our senior executive staff could delay our obtaining FDA approval, our introducing the Delcath chemosaturation system commercially and our generating revenues and profits. Competition for experienced personnel is intense. If we cannot retain our current personnel or attract additional experienced personnel, our ability to compete could be adversely affected.

Risks Related to Patents, Trade Secrets and Proprietary Rights

Our success depends in part on our ability to obtain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties and commercialize the Delcath chemosaturation system prior to the expiration of our patent protection.

Our patent portfolio consists of seven U.S. patents, one pending Patent Cooperation Treaty application, 22 issued foreign counterpart patents and four pending foreign counterpart patent applications. Certain of our U.S., European and other foreign patents have already expired and other U.S. patents relating to the Delcath chemosaturation system will expire beginning in 2012 through 2016.

Due to the uncertainty of the patent prosecution process, there are no guarantees that any of our pending patent applications will result in the issuance of a patent. Even if we are successful in obtaining a patent, there is no assurance that it will be upheld if later challenged or will provide significant protection or commercial advantage. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed.

Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If a third party claims that we infringed its patents, any of the following may occur:

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor's patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

If others file patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could also be costly and could divert our attention from our business. If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources. Use of our limited funds to enforce or to defend our intellectual property rights or to defend against legal proceedings alleging infringement of third party proprietary rights may also affect our financial condition adversely.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before the Delcath chemosaturation system or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our U.S. patent rights have corresponding patent rights effective in Europe or other foreign jurisdictions.

Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

Since we rely solely on trade secret protection in the EEA, our inability to maintain this trade secret protection will significantly limit our ability to commercialize the Delcath chemosaturation system in the EEA.

We presently only have valid issued patents for the current version of the Delcath chemosaturation system in the United States. Without patent protection in the EEA, the Delcath chemosaturation system will only be covered by trade secret protection. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition,

some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge or that we will have adequate remedies for any such breach.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If we are not successful in maintaining the confidentiality of our technology, the loss of trade secret protection or know-how relating to the Delcath chemosaturation system will significantly impair our ability to commercialize the Delcath chemosaturation system in the EEA, and our value and results of operations will be harmed.

Similar considerations apply in any other foreign country where we receive approval. Since we do not have valid issued patents for the current version of the Delcath chemosaturation system in these countries, our ability to successfully commercialize the Delcath chemosaturation system will depend on our ability to maintain trade secret protection in these markets.

Risks Related to Products Liability

We may be the subject of product liability claims or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities.

Our business exposes us to potential liability risks that may arise from the testing, manufacture, marketing, sale and use of the Delcath chemosaturation system. In addition, because the Delcath chemosaturation system is intended for use in patients with cancer, there is an increased risk of death among the patients treated with our system which may increase the risk of product liability lawsuits. We may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our system on patients are not properly trained or are negligent in the use of our system, the patient may be injured through the use of our system, which may subject us to claims. Were such a claim asserted we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and/or limit our ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue. A successful products liability claim or product recall would have a material adverse effect on our business, financial condition and results of operations. We currently carry product liability and clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

Risks Related to Our Common Stock

Our stock price and trading volume may be volatile, which could result in unpredictable pricing of our equity securities.

The equity markets may experience periods of volatility, which could result in highly variable and unpredictable pricing of equity securities. The market price of our common stock could change in ways that may or may not be related to our business, our industry or our operating performance and financial condition. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include:

- results of our clinical trials;
- regulatory delays, non-acceptance or non-approval of our product;
- manufacturing difficulties;

- unexpected adverse events caused by the Delcath chemosaturation system;
- product recalls;
- actual or anticipated quarterly variations in our operating results;
- changes in expectations as to our future financial performance or changes in financial estimates, if any, of public market analysts;
- announcements relating to our business or the business of our competitors;
- a challenge to one of our patents, either in court or via administrative proceedings in the United States Patent and Trademark Office;
- conditions generally affecting the healthcare and cancer treatment industries;
- the success of our operating strategy;
- our ability to repay our debt;
- future sales of equity or equity-related securities; and
- general financial, economic, domestic, international and other market conditions.

Many of these factors are beyond our control, and we cannot predict their potential impact on the price of our common stock. We cannot assure you that the market price of our common stock will not fluctuate or decline significantly in the future.

Our insiders beneficially own a significant portion of our stock.

As of March 31, 2011, our executive officers, directors and affiliated persons beneficially owned approximately [•]% of our common stock. As a result, our executive officers, directors and affiliated persons will have significant influence to:

- elect or defeat the election of our directors;
- amend or prevent amendment of our certificate of incorporation or by-laws;
- effect or prevent a merger, sale of assets or other corporate transaction; and
- affect the outcome of any other matter submitted to the stockholders for vote.

Sales of significant amounts of shares held by our directors and executive officers, or the prospect of these sales, could adversely affect the market price of our common stock.

Our warrants contain anti-dilution provisions that, if triggered, could cause dilution to our existing stockholders.

The warrants issued in our September 2007 and June 2009 private placements contain anti-dilution provisions. The September 2007 warrants are subject to "full ratchet" protection upon certain equity issuances below $3.44 per share (as may be further adjusted). The June 2009 warrants are subject to an exercise price adjustment upon certain equity issuances below $3.60 per share (as may be further adjusted). In addition to the potential dilutive effect of these provisions, there is the potential that a large number of the shares may be sold in the public market at any given time, which could place additional downward pressure on the trading price of our common stock.

Anti-takeover provisions in our Certificate of Incorporation and By-laws and under our stockholder rights agreement may reduce the likelihood of a potential change of control, or make it more difficult for our stockholders to replace management.

Certain provisions of our Certificate of Incorporation and By-laws and of our stockholders rights agreement could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of our stockholders might favor a change in management. These provisions include:

- providing for a staggered board; and
- authorizing the board of directors to fill vacant directorships or increase the size of our board of directors.

Furthermore, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. Our board's ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

We also have a stockholder rights agreement that could have the effect of substantially increasing the cost of acquiring us unless our board of directors supports the transaction even if the holders of a majority of our common stock are in favor of the transaction.

Our common stock is listed on The NASDAQ Capital Market.

If we fail to meet the requirements of The NASDAQ Capital Market for continued listing, our common stock could be delisted. To keep such listing, we are required to maintain: (i) a minimum bid price of $1.00 per share, (ii) a certain public float, (iii) a certain number of round lot shareholders and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least $500,000, a market value of listed securities of at least $35 million or a stockholders' equity of at least $2.5 million. We are presently in compliance with these requirements.

We are also required to maintain certain corporate governance requirements. In the event that in the future we are notified that we no longer comply with NASDAQ's corporate governance requirements, and we fail to regain compliance within the applicable cure period, our common stock could be delisted from The NASDAQ Capital Market.

If our common stock is delisted from The NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on The NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock were delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future.

We currently intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. Our board of directors will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on our profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our board of directors. Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that we may authorize and issue. We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment.

The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings.

We are not restricted from issuing additional shares of our common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of March 31, 2011, we had an aggregate of 26,843,323 shares of common stock authorized but unissued. Subject to certain volume limitations imposed by The NASDAQ Capital Market, we may issue all of these shares without any action or approval by our shareholders. We may expand our business through complementary or strategic acquisitions of other companies and assets, and we may issue shares of common stock in connection with those acquisitions or otherwise. The market price of our common stock could decline as a result of our issuance of a large number of shares of common stock, particularly if the per share consideration we receive for the stock we issue is less than the per share book value of our common stock or if we are not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share we are generating before we issue the additional shares. In addition, any shares issued in connection with these activities, the exercise of stock options or otherwise would dilute the percentage ownership held by our investors. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our common stock.

Risks Related to This Offering

Our management team will have broad discretion over the use of the net proceeds from this offering.

Our management will use its discretion to direct the net proceeds from this offering. We intend to use the net proceeds from the sale of the shares for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. Our management’s judgments may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

Investors in this offering will experience immediate and substantial dilution.

The public offering price of the securities offered pursuant to this prospectus supplement is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of common stock in this offering, you will incur immediate and substantial dilution in the pro forma net tangible book value per share of common stock from the price per share that you pay for the common stock. If the holders of outstanding options exercise those options at prices below the public offering price, you will incur further dilution.

USE OF PROCEEDS

We estimate that the net proceeds from this offering, after deducting underwriter fees and estimated offering expenses of approximately $, will be approximately $ (or approximately $ if the underwriter exercises its overallotment option in full). We intend to use the net proceeds from the sale of the shares for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital.

DIVIDEND POLICY

We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We currently intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes.

DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the adjusted net tangible book value per share of our common stock after this offering.

The net tangible book value of our common stock as of March 31, 2011, was approximately $28,660,413 million, or approximately $0.67 per share. Net tangible book value per share represents the amount of our total tangible assets, excluding goodwill and intangible assets, less total liabilities divided by the total number of shares of our common stock outstanding.

Dilution per share to new investors represents the difference between the amount per share paid by purchasers for our common stock in this offering and the net tangible book value per share of our common stock immediately following the completion of this offering.

After giving effect to the sale of shares of common stock offered by this prospectus supplement at an offering price of $ per share in connection with this offering and after deducting the estimated underwriting discounts and our estimated offering expenses, our pro forma net tangible book value as of March 31, 2011 would have been approximately $ or approximately $ per share. This represents an immediate increase in net tangible book value of approximately $ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $ per share to purchasers of our common stock in this offering, as illustrated by the following table:

Offering price per share	$
Net tangible book value per share as of March 31, 2011	$
Increase per share attributable to new investors	$
Pro forma net tangible book value per share as of March 31, 2011 after giving effect to this offering	$
Dilution per share to new investors	$

The discussion of dilution, and the table quantifying it, assume no exercise of any outstanding options or warrants or other potentially dilutive securities. The exercise of potentially dilutive securities having an exercise price less than the offering price would increase the dilutive effect to new investors.

The table above excludes the following potentially dilutive securities as of March 31, 2011:

- 4,140,629 shares issuable upon the exercise of stock options at a weighted average exercise price of $5.07 per share; and
- 2,512,934 shares issuable upon the exercise of outstanding warrants or options to purchase warrants at a weighted average exercise price of $3.51 per share.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of March 31, 2011 on a historical basis and as adjusted to give effect to this offering and the application of the estimated net proceeds of this offering as described under "Use of Proceeds." This table should be read in conjunction with "Management's Discussion and Analysis of Results of Operations and Financial Condition" and the consolidated financial statements and notes thereto included in our Quarterly Report on Form 10-Q for the three months ended March 31, 2011, which is incorporated by reference herein.

	As of March 31, 2011	
	Historical	As Adjusted
	(unaudited)	
Cash and cash equivalents	$ 39,284,758	$
Warrant liability	$ 12,039,357	$
Stockholders' equity:		
Preferred stock, $0.01 par value: 10,000,000 shares authorized; no shares issued and outstanding	$ —	$ —
Common stock, $0.01 par value: 70,000,000 shares authorized; 43,156,677 shares issued and 42,977,787 shares outstanding at March 31, 2011; 48,156,677 shares issued and 47,977,787 shares outstanding as adjusted	431,567	
Additional paid-in capital	146,217,572	
Deficit accumulated during the development stage	(117,903,422)	
Treasury stock at cost, 28,100 shares at March 31, 2011	(51,103)	
Accumulated other comprehensive loss	(34,200)	
Total stockholders' equity	$ 28,660,414	$
Total capitalization	$ 43,283,654	$

PRICE RANGE OF COMMON STOCK

Our common stock is listed and traded on The NASDAQ Capital Market under the ticker symbol "DCTH." The following table sets forth the high and low last reported sales prices of our common stock for the fiscal quarters indicated as reported on The NASDAQ Capital Market:

Common Stock Price Range

	2011	
	High	Low
Quarter ended March 31, 2011	$ 11.44	$6.18
Quarter ended June 30, 2011	8.63	4.98
Quarter ended September 30, 2011 (through July 13, 2011)	6.37	5.09

	2010	
	High	Low
Quarter ended March 31, 2010	$ 8.41	$4.31
Quarter ended June 30, 2010	16.18	6.34
Quarter ended September 30, 2010	8.69	5.53
Quarter ended December 31, 2010	11.27	7.20

	2009	
	High	Low
Quarter ended March 31, 2009	$ 1.95	$1.18
Quarter ended June 30, 2009	3.98	1.78
Quarter ended September 30, 2009	5.05	2.81
Quarter ended December 31, 2009	6.19	4.02

The reported last sale price of our common stock on The NASDAQ Capital Market on July 13, 2011 was $6.28 per share. On [•], 2011 there were [•] stockholders of record of our common stock.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement dated July 14, 2011, between us and Jefferies & Company, Inc., as underwriter, we have agreed to sell to the underwriter and the underwriter has agreed to purchase from us the entire 5,000,000 shares of our common stock offered by this prospectus supplement.

The underwriting agreement provides that the obligations of the underwriter are subject to certain conditions precedent such as the receipt by the underwriter of officers' certificates and legal opinions and approval of certain legal matters by its counsel. The underwriting agreement provides that the underwriter will purchase all of the shares, other than those shares covered by the overallotment option described below, if any of them are purchased. We have agreed to indemnify the underwriter and certain of its controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriter may be required to make in respect of those liabilities.

The underwriter is offering the shares of our common stock subject to its acceptance of the shares from us and subject to prior sale. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriter has advised us that it does not intend to confirm sales to any account over which it exercises discretionary authority.

The underwriter proposes to offer the shares of our common stock hereby from time to time for sale in one or more transactions on The NASDAQ Capital Market, in the over-the-counter market, through negotiated transactions or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices, subject to receipt and acceptance by it and subject to its right to reject any order in whole or in part. The underwriter may effect such transactions by selling the shares to or through dealers and such dealers may receive compensation in the form of discounts, concessions, or commissions from the underwriter and/or purchasers of shares for whom they may act as agents or to whom they may sell as principal.

Commission and Expenses

In connection with the sale of the shares of common stock offered hereby, the underwriter may be deemed to have received compensation in the form of underwriting discounts.

The expenses of the offering are estimated to be approximately $. We are responsible for all expenses related to the offering, whether or not it is completed.

Listing

Our common stock is listed on The NASDAQ Capital Market under the trading symbol "DCTH."

Option to Purchase Additional Shares

We have granted to the underwriter an option, exercisable for 30 days from the date of this prospectus supplement, to purchase up to an aggregate of 750,000 additional shares of our common stock at $ per share. This option may be exercised only if the underwriter sells more shares than the total number set forth on the cover page of this prospectus supplement.

No Sales of Similar Securities

We, our executive officers and our directors have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended, or
- otherwise dispose of any shares of our common stock, options or warrants to acquire shares of our common stock, or securities exchangeable or exercisable for or convertible into shares of our common stock currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus supplement without the prior written consent of the underwriter.

These restrictions terminate after the close of trading of the shares of our common stock on and including the 90th day after the date of this prospectus supplement. However, subject to certain exceptions, in the event that either:

- during the last 17 days of the 90-day restricted period, we issue an earnings release or material news or a material event relating to us occurs, or
- prior to the expiration of the 90-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day restricted period,

then in each case the 90-day restricted period will be extended until the expiration of the 18-day period beginning on the date of the issuance of the earnings release or the occurrence of the material news or event, as applicable, unless the underwriter waives, in writing, such extension.

The underwriter may, in its sole discretion and at any time or from time to time before the termination of the 90-day period, without public notice, release all or any portion of the securities subject to lock-up agreements. Other than the exceptions specified in the lock-up agreements, there are no existing agreements between the underwriter and us or any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the restricted period.

These restrictions are subject to certain specified exceptions, including the purchase or sale of our securities pursuant to a plan, contract or instruction that satisfies all of the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act.

Stabilization

The underwriter has advised us that, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in transactions, including overallotment, stabilizing bids, syndicate covering transactions or the imposition of penalty bids, which may have the effect of stabilizing or maintaining the market price of our common stock at a level above that which might otherwise prevail in the open market. Overallotment involves syndicate sales in excess of the offering size, which creates a syndicate short position. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriter's option to purchase additional shares of our common stock in this offering. The underwriter may close out any covered short position by either exercising its option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which it may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriter must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of our common stock on behalf of the underwriter for the purpose of fixing or maintaining the price of our common stock. A syndicate covering transaction is the bid for or the purchase of shares of our common stock on behalf of the underwriter to reduce a short position incurred by the underwriter in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriter to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if shares of our common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor the underwriter makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriter is not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on web sites or through online services maintained by the underwriter or its affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriter may agree with us to allocate a specific number of shares of our common stock for sale to online brokerage account holders. Other than the prospectus in electronic format, the information on the underwriter's web sites and any information contained in any other web site maintained by the underwriter is not part of this prospectus supplement, has not been approved and/or endorsed by us or the underwriter and should not be relied upon by investors.

Affiliations

The underwriter or its affiliates from time to time may in the future provide investment banking, commercial lending and financial advisory services to us and our affiliates in the ordinary course of business. The underwriter and its affiliates, as applicable, will receive customary compensation in connection with such services. In the course of its businesses, the underwriter and its affiliates may actively trade our securities for their own account or for the accounts of customers, and, accordingly, the underwriter and its affiliates may at any time hold long or short positions in such securities.

Notice to Investors

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (as defined below) (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, an offer of our common stock to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to our common stock which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive if they have been implemented in the Relevant Member State:

(a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

(c) to fewer than 100 natural or legal persons per Relevant Member State (other than qualified investors as defined in the Prospectus Directive); or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of our common stock shall result in a requirement for the publication by us or the underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of our common stock to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and our common stock to be offered so as to enable an investor to decide to purchase or subscribe our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

United Kingdom

Shares of our common stock may not be offered or sold and will not be offered or sold to any persons in the United Kingdom other than to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or as agent) for the purposes of their businesses or otherwise in circumstances which have not resulted or will not result in an offer to the public in the United Kingdom within the meaning of the Financial Services and Markets Act 2000, or the FSMA.

In addition, any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) in connection with the issue or sale of shares of our common stock may only be communicated or caused to be communicated in circumstances in which Section 21(1) of the FSMA does not apply to us. Without limitation to the other restrictions referred to herein, this prospectus supplement is directed only at (1) persons outside the United Kingdom or (2) persons who:

(a) are qualified investors as defined in section 86(7) of FSMA, being persons falling within the meaning of article 2.1(e)(i), (ii) or (iii) of the Prospectus Directive; and

(b) are either persons who fall within article 19(1) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or Order, or are persons who fall within article 49(2)(a) to (d) ("high net worth companies, unincorporated associations, etc.") of the Order; or

(c) to whom it may otherwise lawfully be communicated in circumstances in which Section 21(1) of the FSMA does not apply.

Without limitation to the other restrictions referred to herein, any investment or investment activity to which this offering circular relates is available only to, and will be engaged in only with, such persons, and persons within the United Kingdom who receive this communication (other than persons who fall within (2) above) should not rely or act upon this communication.

Germany

Any offer or solicitation of securities within Germany must be in full compliance with the German Securities Prospectus Act (Wertpapierprospektgesetz — WpPG). The offer and solicitation of securities to the public in Germany requires the publication of a prospectus that has to be filed with and approved by the German Federal Financial Services Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht — BaFin). This prospectus supplement has not been and will not be submitted for filing and approval to the BaFin and, consequently, will not be published. Therefore, this prospectus supplement does not constitute a public offer under the German Securities Prospectus Act (Wertpapierprospektgesetz). This prospectus supplement and any other document relating to our common stock, as well as any information contained therein, must therefore not be supplied to the public in Germany or used in connection with any offer for subscription of our common stock to the public in Germany, any public marketing of our common stock or any public solicitation for offers to subscribe for or otherwise acquire our common stock. This prospectus supplement and other offering materials relating to the offer of our common stock are strictly confidential and may not be distributed to any person or entity other than the designated recipients hereof.

France

This prospectus has not been prepared in the context of a public offering of financial securities in France within the meaning of Article L.411-1 of the French Code Monétaire et Financier and Title I of Book II of the Règlement Général of the Autorité des marchés financiers (the "AMF") and therefore has not been and will not be filed with the AMF for prior approval or submitted for clearance to the AMF. Consequently, the shares of our common stock may not be, directly or indirectly, offered or sold to the public in France and offers and sales of the shares of our common stock may only be made in France to qualified investors (investisseurs qualifiés) acting for their own, as defined in and in accordance with Articles L.411-2 and D.411-1 to D.411-4, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code Monétaire et Financier. Neither this prospectus nor any other offering material may be released, issued or distributed to the public in France or used in connection with any offer for subscription on sale of the shares of our common stock to the public in France. The subsequent direct or indirect retransfer of the shares of our common stock to the public in France may only be made in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code Monétaire et Financier.

Sweden

This is not a prospectus under, and has not been prepared in accordance with the prospectus requirements provided for in, the Swedish Financial Instruments Trading Act [lagen (1991:980) om handel med finasiella instrument] nor any other Swedish enactment. Neither the Swedish Financial Supervisory Authority nor any other Swedish public body has examined, approved, or registered this document.

LEGAL MATTERS

The validity of our common stock offered in this offering and certain other legal matters will be passed upon for us by Skadden, Arps, Slate, Meagher & Flom LLP, New York, New York. Certain legal matters will be passed upon for the underwriter by Goodwin Procter LLP, New York, New York.

EXPERTS

The financial statements of Delcath Systems, Inc. as of and for the year ended December 31, 2010 appearing in our Annual Report on Form 10-K for the year ended December 31, 2010 and the effectiveness of our internal control over financial reporting as of December 31, 2010 have been audited by Ernst & Young LLP, an independent registered public accounting firm, as set forth in their reports thereon, included therein, and incorporated herein by reference.

The financial statements of Delcath Systems, Inc. as of December 31, 2009 and for the years ended December 31, 2009 and 2008 and cumulative from inception (August 5, 1988) to December 31, 2009 appearing in our Annual Report on Form 10-K for the year ended December 31, 2009 (including schedule appearing therein) and the effectiveness of our internal control over financial reporting as of December 31, 2009 have been audited by CCR LLP, an independent registered public accounting firm, as set forth in their reports thereon, included therein, and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firms as experts in accounting and auditing.

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PROSPECTUS

$100,000,000

Common Stock
Preferred Stock
Warrants
Debt Securities
Stock Purchase Contracts

Delcath Systems, Inc. (the "Company") may offer to sell from time to time common stock, preferred stock, warrants, debt securities and stock purchase contracts. The preferred stock of the Company may be convertible into common stock or preferred stock of another series.

The Company may offer securities at an aggregate offering price of up to $100,000,000. The common stock, preferred stock, warrants, debt securities and stock purchase contracts of the Company may be offered separately or together, in multiple series, in amounts, at prices and on terms that will be set forth in one or more prospectus supplements to this prospectus.

This prospectus describes some of the general terms that may apply to these securities and the general manner in which they may be offered. Each time the Company sells securities, a prospectus supplement will be provided that will contain specific information about the terms of any securities offered and the specific manner in which the securities will be offered. The prospectus supplement will also contain information, where appropriate, about material United States federal income tax consequences relating to, and any listing on a securities exchange of, the securities covered by the prospectus supplement. The prospectus supplement may add to, update or change the information in this prospectus. You should read this prospectus and any prospectus supplement carefully before you invest in our securities. This prospectus may not be used to sell securities unless accompanied by a prospectus supplement.

The Company may offer the securities directly to investors, through agents designated from time to time by the Company, or to or through underwriters or dealers. If any agents, underwriters, or dealers are involved in the sale of any of the securities, their names, and any applicable purchase price, fee, commission or discount arrangement with, between or among them will be set forth, or will be calculable from the information set forth, in an accompanying prospectus supplement. For more detailed information, see "Plan of Distribution."

Our common stock is traded on the NASDAQ Capital Market under the symbol "DCTH." On March 23, 2010, the last reported sale price of our common stock on the NASDAQ Capital Market was $6.44.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties referenced under the heading "Risk Factors" beginning on page 3 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 13, 2010.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission using a “shelf” registration process. Under this shelf process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of $100,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading “Where You Can Find More Information.”

You should rely only on the information contained in this prospectus and the accompanying prospectus supplement or incorporated by reference in these documents. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. If anyone provides you with different, inconsistent or unauthorized information or representations, you must not rely on them. This prospectus and the accompanying prospectus supplement are an offer to sell only the securities offered by these documents, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or any prospectus supplement is current only as of the date on the front of those documents.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the section entitled "Risk Factors," any applicable prospectus supplement and the documents that we incorporate by reference into this prospectus and the prospectus supplement, before making an investment decision.

DELCATH SYSTEMS, INC.

We are a development stage company that has developed an innovative system designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body. Since our inception we have focused our efforts on the development of a single product, the Delcath Percutaneous Hepatic Perfusion System, or The Delcath PHP System which provides regional therapy by isolating the circulatory system of the liver in order to directly deliver high doses of therapeutic agents, while controlling the systemic exposure of those agents. The Delcath PHP System is minimally invasive and repeatable. We believe that the Delcath PHP System is a platform technology that may have broader applicability to other organs and body regions. In our initial application, the Delcath PHP System isolates the liver from the patient's general circulatory system in order to deliver high doses of melphalan hydrochloride, an approved chemotherapeutic drug, directly to the liver. We are currently conducting a Phase III trial and a multi-arm Phase II trial of the Delcath PHP System with melphalan in patients with liver cancers. The Phase III and Phase II clinical trials are subject to the terms and conditions of a Cooperative Research and Development Agreement, the CRADA, between us and the National Cancer Institute, or NCI. The Delcath PHP System is not currently approved by the U.S. Food and Drug Administration (FDA), and it cannot be marketed in the United States without prior FDA approval.

Our most advanced trial is a randomized Phase III multi-center study led by the NCI for patients with metastatic ocular and cutaneous melanoma in the liver. The FDA has granted the Delcath PHP System with melphalan Fast Track designation for the treatment of hepatic tumors secondary to melanoma. We have also been granted four orphan drug designations, including for the drug melphalan for the treatment of patients with ocular and cutaneous melanoma.

We began enrollment of our Phase III clinical trial in 2006 to support the FDA approval process for the Delcath PHP System. As of October 20, 2009, we enrolled all of the 92 patients called for under a Special Protocol Assessment, or SPA, granted by the FDA. We expect to submit our application to the FDA by mid-2010 for the treatment of hepatic tumors secondary to melanoma with the Delcath.

The FDA regulates the Delcath PHP System as a combination product: the combination of a medical device and a drug. Before we can market the Delcath PHP System, we must obtain FDA approval of the drug and device under a Section 505(b)(2) new drug application, or NDA.

We are also conducting a separate Phase II clinical trial of the Delcath PHP System with melphalan in patients with primary and metastatic hepatic malignancies (liver cancer), stratified into four arms: neuroendocrine tumors (carcinoid and islet cell tumors), hepatocellular carcinoma (primary liver cancer), ocular or cutaneous melanoma (eye or skin cancer who have been previously treated with regional therapy using melphalan), and metastatic adenocarcinoma (glandular cancer). In the future, we plan to conduct preclinical and clinical trials to treat liver cancer using the Delcath PHP System with chemotherapy agents other than melphalan.

Our principal executive office is located at 600 Fifth Avenue, 23rd Floor, New York, NY 10020. Our telephone number is (212) 489-2100. Our website address is www.delcath.com. Information contained in, or accessible through, our website does not constitute a part of this prospectus.

Unless the context indicates otherwise, as used in this prospectus, the terms “Delcath Systems,” “we,” “us” and “our” refer to Delcath Systems, Inc., a Delaware corporation. Delcath® is a registered trademark of Delcath Systems, Inc. and we use The Delcath PHP System and the Delcath Systems logo as trademarks in the United States and other countries. All other trademarks or trade names, if any, referred to in this prospectus are the property of their respective owners.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risk factors set forth in the documents and reports filed by us with the Securities and Exchange Commission, which we refer to as the SEC, that are incorporated by reference into this prospectus, as well as any risks described in any applicable prospectus supplement, before deciding whether to buy our securities. Additional risks not known to us or that we believe are immaterial may also significantly impair our business operations and could result in a complete loss of your investment.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, any prospectus supplement and the documents incorporated by reference into this prospectus contain certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this prospectus and the other documents incorporated by reference that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 in Item 1A under "Risk Factors" as well as in Item 7A "Qualitative and Quantitative Disclosures About Market Risk," and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- the progress and results of our research and development programs;
- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the results and timing of our clinical trials and the commencement of future clinical trials; and
- submission and timing of applications for regulatory approval.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this prospectus or, in the case of documents incorporated by reference, as of the date of such documents. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of a registration statement we filed with the SEC. You should rely only on the information contained in this prospectus, any applicable prospectus supplement or documents incorporated by reference into this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of securities.

We file reports, proxy statements and other information with the SEC. You may read and copy any reports, proxy statements or other information filed by us at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at (800) SEC-0330. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including Delcath Systems, Inc. The address of the SEC website is http://www.sec.gov.

Important Information Incorporated By Reference

The SEC allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The SEC file number for the documents incorporated by reference in this prospectus is 001-16133. The documents incorporated by reference into this prospectus contain important information that you should read about us.

The following documents are incorporated by reference into this document:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and filed with the SEC on February 26, 2010;
- Our Current Reports on Form 8-K, filed on February 10, 2010, February 24, 2010 and March 2, 2010; and
- The description of our common stock, which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A12B, filed with the SEC on September 22, 2000, including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial registration statement and prior to effectiveness of the registration statement, or (ii) from the date of this prospectus but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus, other than exhibits which are specifically incorporated by reference into such documents. Requests should be directed to Controller at Delcath Systems, Inc., 600 Fifth Avenue, 23rd Floor, New York 10020 or by calling us at 212-489-2100.

USE OF PROCEEDS

Unless we provide otherwise in a supplement to this prospectus, we intend to use the net proceeds from the sale of our securities covered by this prospectus for general corporate purposes, including, but not limited to, obtaining regulatory approvals, commercialization of our products, funding of our clinical trials, capital expenditures and working capital.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we may include in any applicable prospectus supplement and in any related free writing prospectuses, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms summarized below will apply generally to any debt securities that we may offer, we will describe the particular terms of any debt securities in more detail in the applicable prospectus supplement. The terms of any debt securities offered under a prospectus supplement may differ from the terms described below.

We may issue debt securities from time to time in one or more distinct series. The debt securities may be senior debt securities or subordinated debt securities. Senior debt securities may be issued under a senior indenture and subordinated debt securities may be issued under a subordinated indenture. If we issue debt securities pursuant to an indenture, in the applicable prospectus supplement we will specify the trustee under such indenture. We will include in a supplement to this prospectus the specific terms of debt securities being offered, including the terms, if any, on which debt securities may be convertible into or exchangeable for common stock, preferred stock or other debt securities. The statements and descriptions in this prospectus or in any prospectus supplement regarding provisions of debt securities and any indentures are summaries of these provisions, do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of the debt securities and the indentures (including any amendments or supplements we may enter into from time to time which are permitted under the debt securities or any indenture).

Unless otherwise specified in a prospectus supplement, the debt securities will be direct unsecured obligations of the Company. Any debt securities designated as senior will rank equally with any of our other senior and unsubordinated debt. Any debt securities designated as subordinated will be subordinate and junior in right of payment to any senior indebtedness. There may be subordinated debt securities that are senior or junior to other series of subordinated debt securities.

The applicable prospectus supplement will set forth the terms of the debt securities or any series thereof, including, if applicable:

- the title of the debt securities and whether the debt securities will be senior debt securities or subordinated debt securities;
- any limit upon the aggregate principal amount of the debt securities;
- whether the debt securities will be issued as registered securities, bearer securities or both, and any restrictions on the exchange of one form of debt securities for another and on the offer, sale and delivery of the debt securities in either form;
- the date or dates on which the principal amount of the debt securities will mature;
- if the debt securities bear interest, the rate or rates at which the debt securities bear interest, or the method for determining the interest rate, and the date or dates from which interest will accrue;
- if the debt securities bear interest, the dates on which interest will be payable, or the method for determining such dates, and the regular record dates for interest payments;
- the place or places where the payment of principal, any premium and interest will be made, where the debt securities may be surrendered for transfer or exchange and where notices or demands to or upon us may be served;
- any optional redemption provisions, which would allow us to redeem the debt securities in whole or in part;
- any sinking fund or other provisions that would obligate us to redeem, repay or purchase the debt securities;

- if the currency in which the debt securities will be issuable is United States dollars, the denominations in which any registered securities will be issuable, if other than denominations of $1,000 and any integral multiple thereof, and the denominations in which any bearer securities will be issuable, if other than the denomination of $5,000;
- if other than the entire principal amount, the portion of the principal amount of debt securities which will be payable upon a declaration of acceleration of the maturity of the debt securities;
- the events of default and covenants relevant to the debt securities, including, the inapplicability of any event of default or covenant set forth in the indenture relating to the debt securities, or the applicability of any other events of defaults or covenants in addition to the events of default or covenants set forth in the indenture relating to the debt securities;
- the name and location of the corporate trust office of the applicable trustee under the indenture for such series of notes;
- if other than United States dollars, the currency in which the debt securities will be paid or denominated;
- if the debt securities are to be payable, at our election or the election of a holder of the debt securities, in a currency other than that in which the debt securities are denominated or stated to be payable, the terms and conditions upon which that election may be made, and the time and manner of determining the exchange rate between the currency in which the debt securities are denominated or stated to be payable and the currency in which the debt securities are to be so payable;
- the designation of the original currency determination agent, if any;
- if the debt securities are issuable as indexed securities, the manner in which the amount of payments of principal, any premium and interest will be determined;
- if the debt securities do not bear interest, the dates on which we will furnish to the applicable trustee the names and addresses of the holders of the debt securities;
- if other than as set forth in an indenture, provisions for the satisfaction and discharge or defeasance or covenant defeasance of that indenture with respect to the debt securities issued under that indenture;
- the date as of which any bearer securities and any global security will be dated if other than the date of original issuance of the first debt security of a particular series to be issued;
- whether and under what circumstances we will pay additional amounts to non-United States holders in respect of any tax assessment or government charge;
- whether the debt securities will be issued in whole or in part in the form of a global security or securities and, in that case, any depositary and global exchange agent for the global security or securities, whether the global form shall be permanent or temporary and, if applicable, the exchange date;
- if debt securities are to be issuable initially in the form of a temporary global security, the circumstances under which the temporary global security can be exchanged for definitive debt securities and whether the definitive debt securities will be registered securities, bearer securities or will be in global form and provisions relating to the payment of interest in respect of any portion of a global security payable in respect of an interest payment date prior to the exchange date;
- the extent and manner to which payment on or in respect of debt securities will be subordinated to the prior payment of our other liabilities and obligations;
- whether payment of any amount due under the debt securities will be guaranteed by one or more guarantors, including one or more of our subsidiaries;
- whether the debt securities will be convertible and the terms of any conversion provisions;

- the forms of the debt securities; and
- any other terms of the debt securities, which terms shall not be inconsistent with the requirements of the Trust Indenture Act of 1939, as amended.

This prospectus is part of a registration statement that does not limit the aggregate principal amount of debt securities that we may issue and provides that we may issue debt securities from time to time in one or more series under one or more indentures, in each case with the same or various maturities, at par or at a discount. Unless indicated in a prospectus supplement, we may issue additional debt securities of a particular series without the consent of the holders of the debt securities of such series outstanding at the time of the issuance. Any such additional debt securities, together with all other outstanding debt securities of that series, will constitute a single series of debt securities under the applicable indenture.

We intend to disclose any restrictive covenants for any issuance or series of debt securities in the applicable prospectus supplement.

DESCRIPTION OF CAPITAL STOCK

The following description of our common stock and preferred stock, together with the additional information we include in any applicable prospectus supplement and in any related free writing prospectuses, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated By-Laws, which are exhibits to the registration statement of which this prospectus forms a part, and by applicable law. We refer in this section to our Amended and Restated Certificate of Incorporation, as amended, as our certificate of incorporation, and we refer to our Amended and Restated By-Laws as our by-laws. The terms of our common stock and preferred stock may also be affected by Delaware law.

Authorized Capital Stock

Our authorized capital stock consists of 70,000,000 shares of our common stock, $0.01 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.01 par value per share. As of March 22, 2010, we had 36,655,734 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

Voting

Holders of our common stock are entitled to one vote per share on matters to be voted on by stockholders and also are entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. Holders of our common stock have exclusive voting rights for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our certificate of incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment or filling vacancies on the board of directors.

Dividends

Holders of common stock are entitled to share ratably in any dividends declared by our board of directors, subject to any preferential dividend rights of any outstanding preferred stock. Dividends consisting of shares of common stock may be paid to holders of shares of common stock. We do not intend to pay cash dividends in the foreseeable future.

Liquidation and Dissolution

Upon our liquidation or dissolution, the holders of our common stock will be entitled to receive pro rata all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock at the time outstanding.

Other Rights and Restrictions

Our common stock has no preemptive or other subscription rights, and there are no conversion rights or redemption or sinking fund provisions with respect to such stock. Our common stock is not subject to redemption by us. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer the stockholder’s shares of common stock. If we issue shares of common stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Listing

Our common stock is listed on The NASDAQ Capital Market under the symbol “DCTH.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

Preferred Stock

Our board of directors has the authority to issue up to 10,000,000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval, none of which are outstanding. Our board of directors may issue preferred stock in one or more series and has the authority to fix the designation and powers, rights and preferences and the qualifications, limitations, or restrictions with respect to each class or series of such class without further vote or action by the stockholders. The ability of our board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management.

If we decide to issue any preferred stock pursuant to this prospectus, we will describe in a prospectus supplement the terms of the preferred stock, including, if applicable, the following:

- the title of the series and stated value;
- the number of shares of the series of preferred stock offered, the liquidation preference per share, if applicable, and the offering price;
- the applicable dividend rate(s) or amount(s), period(s) and payment date(s) or method(s) of calculation thereof;
- the date from which dividends on the preferred stock will accumulate, if applicable;
- any procedures for auction and remarketing;
- any provisions for a sinking fund;
- any applicable provision for redemption and the price or prices, terms and conditions on which preferred stock may be redeemed;
- any securities exchange listing;
- any voting rights and powers;
- whether interests in the preferred stock will be represented by depository shares;
- the terms and conditions, if applicable, of conversion into shares of our common stock, including the conversion price or rate or manner of calculation thereof;
- a discussion of any material U.S. federal income tax considerations;
- the relative ranking and preference as to dividend rights and rights upon our liquidation, dissolution or the winding up of our affairs;
- any limitations on issuance of any series of preferred stock ranking senior to or on a parity with such series of preferred stock as to dividend rights and rights upon our liquidation, dissolution or the winding up of our affairs; and
- any other specific terms, preferences, rights, limitations or restrictions of such series of preferred stock.

Certain Anti-Takeover Provisions of Delaware Law and our Certificate of Incorporation and Bylaws

We are not subject to Section 203 of the Delaware General Corporation Law, which prohibits Delaware corporations from engaging in a wide range of specified transactions with any interested stockholder, defined to include, among others, any person other than such corporation and any of its majority owned subsidiaries who own 15% or more of any class or series of stock entitled to vote generally in the election of directors, unless, among other exceptions, the transaction is approved by (i) our board of directors prior to the date the interested stockholder obtained such status or (ii) the holders of two thirds of the outstanding shares of each class or series of stock entitled to vote generally in the election of directors, not including those shares owned by the interested stockholder.

Staggered Board of Directors

Our certificate of incorporation and by-laws provide that our board of directors be classified into three classes of directors of approximately equal size. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings.

Stockholder Rights Plan

On October 30, 2001, the Company entered into a Rights Agreement with American Stock Transfer & Trust Company (the “Rights Agreement”) in connection with the implementation of the Company’s stockholder rights plan (the “Rights Plan”). The purposes of the Rights Plan are to deter, and protect the Company’s shareholders from, certain coercive and otherwise unfair takeover tactics and to enable the board of directors to represent effectively the interests of shareholders in the event of a takeover attempt. The Rights Plan does not deter negotiated mergers or business combinations that the board of directors determines to be in the best interests of the Company and its shareholders. To implement the Rights Plan, the board of directors declared a dividend of one common stock purchase right (a “Right”) for each share of common stock outstanding at the close of business on November 14, 2001 (the “Record Date”) or issued by the Company on or after such date and prior to the earlier of the Distribution Date, the Redemption Date or the Final Expiration Date (as such terms are defined in the Rights Agreement). The rights expire October 30, 2011. Each Right entitles the registered holder, under specified circumstances, to purchase from the Company for $5.00, subject to adjustment (the “Purchase Price”), a number of shares determined by dividing the then applicable Purchase Price by 50% of the then current market price per share in the event that a person or group announces that it has acquired, or intends to acquire, 15% or more of the Company’s outstanding common stock. On April 9, 2007 the Board of Directors voted to increase the threshold level to 20%.

Authorized But Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions, employee benefit plans and stockholder rights plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

DESCRIPTION OF STOCK PURCHASE CONTRACTS

The following description, together with the additional information that we include in any applicable prospectus supplement and in any related free writing prospectuses, summarizes the material terms and provisions of the stock purchase contracts that we may offer under this prospectus. While the terms we have summarized below will apply generally to any stock purchase contracts that we may offer under this prospectus, we will describe the particular terms of any series of stock purchase contracts in more detail in the applicable prospectus supplement. The terms of any stock purchase contracts offered under a prospectus supplement may differ from the terms described below.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of stock purchase contract that describes the terms of the particular stock purchase contract we are offering before the issuance of the related stock purchase contract. The following summaries of material provisions of the stock purchase contracts are subject to, and qualified in their entirety by reference to, all the provisions of the stock purchase contracts applicable to the stock purchase contracts that we may offer under this prospectus. We urge you to read the applicable prospectus supplements related to the stock purchase contracts that we may offer under this prospectus, as well as any related free writing prospectuses, and the complete stock purchase contracts that contain the terms of the stock purchase contracts.

We may issue stock purchase contracts, including contracts obligating holders to purchase from us and us to sell to the holders, a specified number of shares of common stock or preferred stock at a future date or dates. Alternatively, the stock purchase contracts may obligate us to purchase from holders, and obligate holders to sell to us, a specified or varying number of shares of common stock or preferred stock. The consideration per share of common stock or preferred stock may be fixed at the time the stock purchase contracts are issued or may be determined by a specific reference to a formula set forth in the stock purchase contracts. The stock purchase contracts may provide for settlement by delivery by us or on our behalf of shares of the underlying security, or they may provide for settlement by reference or linkage to the value, performance or trading price of the underlying security. The stock purchase contracts may require us to make periodic payments to the holders of the certain of our securities or vice versa, and such payments may be unsecured or prefunded on some basis and may be paid on a current or on a deferred basis. The stock purchase contracts may require holders to secure their obligations thereunder in a specified manner and may provide for the prepayment of all or part of the consideration payable by holders in connection with the purchase of the underlying security or other property pursuant to the stock purchase contracts.

The securities related to the stock purchase contracts may be pledged to a collateral agent for our benefit pursuant to a pledge agreement to secure the obligations of holders of stock purchase contracts to purchase the underlying security or property under the related stock purchase contracts. The rights of holders of stock purchase contracts to the related pledged securities will be subject to our security interest therein created by the pledge agreement. No holder of stock purchase contracts will be permitted to withdraw the pledged securities related to such stock purchase contracts from the pledge arrangement.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The terms of any warrants offered under a prospectus supplement may differ from the terms described below.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant agreement, including a form of warrant certificate, that describes the terms of the particular warrants we are offering before the issuance of the related warrants. The following summaries of material provisions of the warrants and the warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to the warrants that we may offer under this prospectus. We urge you to read the applicable prospectus supplements related to the warrants that we may offer under this prospectus, as well as any related free writing prospectuses, and the complete warrant agreements and warrant certificates that contain the terms of the warrants.

General

We may issue warrants for the purchase of common stock or preferred stock in one or more series. We may issue warrants independently or together with common stock and preferred stock, and the warrants may be attached to or separate from these securities.

We may evidence each series of warrants by warrant certificates that we will issue under a separate agreement. We may enter into a warrant agreement with a warrant agent. We will indicate the name and address and other information regarding the warrant agent in the applicable prospectus supplement relating to a particular warrants.

If we decide to issue warrants pursuant to this prospectus, we will specify in a prospectus supplement the terms of the warrants, including, if applicable, the following:

- the offering price and aggregate number of warrants offered;
- the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- the date on and after which the warrants and the related securities will be separately transferable;
- the number of shares of stock purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreement and warrants may be modified;
- a discussion of any material U.S. federal income tax considerations of holding or exercising the warrants;

- the terms of the securities issuable upon exercise of the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants may have no rights of holders of the securities purchasable upon such exercise, including, in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase shares of our stock at the exercise price that we describe in the applicable prospectus supplement. Holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. If we so indicate in the applicable prospectus supplement, the warrants may also provide that they may be exercised on a “cashless” or net basis. We will set forth on the reverse side of the warrant certificate, if applicable, and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to us or a warrant agent.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at our offices, the corporate trust office of a warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the common stock or preferred stock purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender shares of common stock or preferred stock as all or part of the exercise price for warrants.

Enforceability of Rights by Holders of Warrants

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

PLAN OF DISTRIBUTION

We may sell the securities offered by this prospectus from time to time in one or more transactions, including without limitation:

- directly to one or more purchasers;
- through agents;
- to or through underwriters, brokers or dealers;
- through a combination of any of these methods.

A distribution of the securities offered by this prospectus may also be effected through the issuance of derivative securities, including without limitation, warrants, subscriptions, exchangeable securities, forward delivery contracts and the writing of options.

In addition, the manner in which we may sell some or all of the securities covered by this prospectus includes, without limitation, through:

- a block trade in which a broker-dealer will attempt to sell as agent, but may position or resell a portion of the block, as principal, in order to facilitate the transaction;
- purchases by a broker-dealer, as principal, and resale by the broker-dealer for its account;
- ordinary brokerage transactions and transactions in which a broker solicits purchasers; or
- privately negotiated transactions.

We may also enter into hedging transactions. For example, we may:

- enter into transactions with a broker-dealer or affiliate thereof in connection with which such broker-dealer or affiliate will engage in short sales of the common stock pursuant to this prospectus, in which case such broker-dealer or affiliate may use shares of common stock received from us to close out its short positions;
- sell securities short and redeliver such shares to close out our short positions;
- enter into option or other types of transactions that require us to deliver common stock to a broker-dealer or an affiliate thereof, who will then resell or transfer the common stock under this prospectus; or
- loan or pledge the common stock to a broker-dealer or an affiliate thereof, who may sell the loaned shares or, in an event of default in the case of a pledge, sell the pledged shares pursuant to this prospectus.

In addition, we may enter into derivative or hedging transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. In connection with such a transaction, the third parties may sell securities covered by and pursuant to this prospectus and an applicable prospectus supplement or pricing supplement, as the case may be. If so, the third party may use securities borrowed from us or others to settle such sales and may use securities received from us to close out any related short positions. We may also loan or pledge securities covered by this prospectus and an applicable prospectus supplement to third parties, who may sell the loaned securities or, in an event of default in the case of a pledge, sell the pledged securities pursuant to this prospectus and the applicable prospectus supplement or pricing supplement, as the case may be.

A prospectus supplement with respect to each offering of securities will state the terms of the offering of the securities, including:

- the name or names of any underwriters or agents and the amounts of securities underwritten or purchased by each of them, if any;
- the public offering price or purchase price of the securities and the net proceeds to be received by us from the sale;
- any delayed delivery arrangements;
- any underwriting discounts or agency fees and other items constituting underwriters' or agents' compensation;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or markets on which the securities may be listed.

The offer and sale of the securities described in this prospectus by us, the underwriters or the third parties described above may be effected from time to time in one or more transactions, including privately negotiated transactions, either:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to the prevailing market prices; or
- at negotiated prices.

General

Any public offering price and any discounts, commissions, concessions or other items constituting compensation allowed or reallowed or paid to underwriters, dealers, agents or remarketing firms may be changed from time to time. Underwriters, dealers, agents and remarketing firms that participate in the distribution of the offered securities may be "underwriters" as defined in the Securities Act. Any discounts or commissions they receive from us and any profits they receive on the resale of the offered securities may be treated as underwriting discounts and commissions under the Securities Act. We will identify any underwriters, agents or dealers and describe their commissions, fees or discounts in the applicable prospectus supplement or pricing supplement, as the case may be.

Underwriters and Agents

If underwriters are used in a sale, they will acquire the offered securities for their own account. The underwriters may resell the offered securities in one or more transactions, including negotiated transactions. These sales may be made at a fixed public offering price or prices, which may be changed, at market prices prevailing at the time of the sale, at prices related to such prevailing market price or at negotiated prices. We may offer the securities to the public through an underwriting syndicate or through a single underwriter. The underwriters in any particular offering will be mentioned in the applicable prospectus supplement or pricing supplement, as the case may be.

Unless otherwise specified in connection with any particular offering of securities, the obligations of the underwriters to purchase the offered securities will be subject to certain conditions contained in an underwriting agreement that we will enter into with the underwriters at the time of the sale to them. The underwriters will be obligated to purchase all of the securities of the series offered if any of the securities are purchased, unless otherwise specified in connection with any particular offering of securities. Any initial offering price and any discounts or concessions allowed, reallowed or paid to dealers may be changed from time to time.

We may designate agents to sell the offered securities. Unless otherwise specified in connection with any particular offering of securities, the agents will agree to use their best efforts to solicit purchases for the period of their appointment. We may also sell the offered securities to one or more remarketing firms, acting as principals for their own accounts or as agents for us. These firms will remarket the offered securities upon purchasing them in accordance with a redemption or repayment pursuant to the terms of the offered securities. A prospectus supplement or pricing supplement, as the case may be will identify any remarketing firm and will describe the terms of its agreement, if any, with us and its compensation.

In connection with offerings made through underwriters or agents, we may enter into agreements with such underwriters or agents pursuant to which we receive our outstanding securities in consideration for the securities being offered to the public for cash. In connection with these arrangements, the underwriters or agents may also sell securities covered by this prospectus to hedge their positions in these outstanding securities, including in short sale transactions. If so, the underwriters or agents may use the securities received from us under these arrangements to close out any related open borrowings of securities.

Dealers

We may sell the offered securities to dealers as principals. We may negotiate and pay dealers' commissions, discounts or concessions for their services. The dealer may then resell such securities to the public either at varying prices to be determined by the dealer or at a fixed offering price agreed to with us at the time of resale. Dealers engaged by us may allow other dealers to participate in resales.

Direct Sales

We may choose to sell the offered securities directly. In this case, no underwriters or agents would be involved.

Institutional Purchasers

We may authorize agents, dealers or underwriters to solicit certain institutional investors to purchase offered securities on a delayed delivery basis pursuant to delayed delivery contracts providing for payment and delivery on a specified future date. The applicable prospectus supplement or pricing supplement, as the case may be will provide the details of any such arrangement, including the offering price and commissions payable on the solicitations.

We will enter into such delayed contracts only with institutional purchasers that we approve. These institutions may include commercial and savings banks, insurance companies, pension funds, investment companies and educational and charitable institutions.

Indemnification; Other Relationships

We may have agreements with agents, underwriters, dealers and remarketing firms to indemnify them against certain civil liabilities, including liabilities under the Securities Act. Agents, underwriters, dealers and remarketing firms, and their affiliates, may engage in transactions with, or perform services for, us in the ordinary course of business. This includes commercial banking and investment banking transactions.

Market-Making, Stabilization and Other Transactions

There is currently no market for any of the offered securities, other than the common stock which is listed on the Nasdaq Capital Market. If the offered securities are traded after their initial issuance, they may trade at a discount from their initial offering price, depending upon prevailing interest rates, the market for similar securities and other factors. While it is possible that an underwriter could inform us that it intends to make a

market in the offered securities, such underwriter would not be obligated to do so, and any such market-making could be discontinued at any time without notice. Therefore, no assurance can be given as to whether an active trading market will develop for the offered securities. We have no current plans for listing of the debt securities, preferred stock or warrants on any securities exchange or on the National Association of Securities Dealers, Inc. automated quotation system; any such listing with respect to any particular debt securities, preferred stock or warrants will be described in the applicable prospectus supplement or pricing supplement, as the case may be.

In connection with any offering of common stock, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, syndicate covering transactions and stabilizing transactions. Short sales involve syndicate sales of common stock in excess of the number of shares to be purchased by the underwriters in the offering, which creates a syndicate short position. “Covered” short sales are sales of shares made in an amount up to the number of shares represented by the underwriters’ over-allotment option. In determining the source of shares to close out the covered syndicate short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Transactions to close out the covered syndicate short involve either purchases of the common stock in the open market after the distribution has been completed or the exercise of the over-allotment option. The underwriters may also make “naked” short sales of shares in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of bids for or purchases of shares in the open market while the offering is in progress for the purpose of pegging, fixing or maintaining the price of the securities.

In connection with any offering, the underwriters may also engage in penalty bids. Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the securities to be higher than it would be in the absence of the transactions. The underwriters may, if they commence these transactions, discontinue them at any time.

Fees and Commissions

In compliance with the guidelines of the Financial Industry Regulatory Authority (the “FINRA”), the aggregate maximum discount, commission or agency fees or other items constituting underwriting compensation to be received by any FINRA member or independent broker-dealer will not exceed 8% of any offering pursuant to this prospectus and any applicable prospectus supplement or pricing supplement, as the case may be; however, it is anticipated that the maximum commission or discount to be received in any particular offering of securities will be significantly less than this amount.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, Skadden, Arps, Slate, Meagher & Flom LLP, New York, New York will provide opinions regarding the authorization and validity of the securities. Skadden, Arps, Slate, Meagher & Flom LLP may also provide opinions regarding certain other matters. Any underwriters will also be advised about legal matters by their own counsel, which will be named in the prospectus supplement.

EXPERTS

CCR LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K for the year ended December 31, 2009, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on CCR LLP's report, given on their authority as experts in accounting and auditing.

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5,000,000 Shares

Common Stock

PROSPECTUS SUPPLEMENT

Sole Book-Running Manager

Jefferies

, 2011